United States Court of Appeals

for the Second Circuit

APPENDIX

ORIGINAL WITH PROOF OF SERVICE

76-6169

UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

and

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

On Appeal from a Judgment of the United States District Court for the Eastern District of New York

JOINT APPENDIX

(Volume II of II - Pages A-405 - A-813)

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DEC 30 1976
SECOND CIRCUIT

COUNSEL PRESS, INC., 55 West 42nd Street, New York, N.Y. 10036 • PE 6-8460

PAGINATION AS IN ORIGINAL COPY

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A A R O N G I L MA N , called as a witness, having been first duly sworn by the Clerk of the Court, took the stand and testified as follows:

DIRECT EXAMINATION

BY MR. EPSTEIN:

Q Mr. Gilman, what is your present occupation?

A I am the President of Interseed Fisheries.

Q What is the business of Interseed Fisheries?

A It's a seafood and shellfish commodity brokerage company.

Q In the past, have you had any connection with the hot smoked whitefish business?

A Yes, sir.

Q What has that connection been?

A I was in the smoked fish business for some thirty years.

Q In what capacity?

A I was the President of Vita Food Products.

Q For that entire thirty years?

A No, sir. For the last fifteen years of my career with Vita Foods.

Q During your career with Vita Foods, have you become familiar with what is or is not commercially acceptable in connection with hot smoked whitefish?

A I believe so.

Q You know from experience what kind of product a merchant will or will not receive in the store or be able to sell; is that correct?

A Yes, sir.

Q Now, Mr. Gilman, have you ever had occasion prior to this time right now to see the fish which has been arrayed on the counsel table over here?

A You mean these specific products?

Q These specific products.

A No, sir.

Q And have you discussed with me or anyone else the method of preparation or anything to do with these fish?

A No, sir.

(continued next page)

Q All right.

Mr. Gilman, I am going to ask you to step down to the counsel table and there are 24 fish right there, the boxes are lettered A through F and I would appreciate it if you would examine the fish any way you feel necessary, taste them, if you wish, and indicate which, if any, of them would be a commercially accepted product.

MR. MC MORROW: I would like to preserve for the record my objection to Mr. Gilman's testimony and to the entire, whatever it is that is going on before us.

THE COURT: Very well.

MR. EINSTEIN: I will ask Mr. Gilman to start with the box that has the letter A on it.

THE WITNESS: Do you want me to look and examine all of the products and look at it and then just tell you from my visual observation which is commercially acceptable?

Q Also taste it, if you feel that's necessary --

MR. MC MORROW: I believe the samples are still tagged, your Honor.

MR. EINSTEIN: Let me place the tags face down to counsel's satisfaction.

THE COURT: It's to make the test useful, if

it can be.

MR. EINSTEIN: We don't want Mr. Gilman to know the cooking parameters.

THE COURT: Maybe, Mr. Rappaport, we can go down to counsel table.

(The witness, counsel, the Court and the court reporter assemble around counsel table and the following occurs:)

MR. MC MORROW: I have one further objection, and that is the boxes are marked Vita and Nova Scotia.

MR. EINSTEIN: That I couldn't help.

Q All right, Mr. Gilman. Would you proceed and I will ask you to the extent possible not to look at the tags that are on the fish.

Why don't you start with box A.

A Box A by appearance, smoking appearance of the finished product I would say is commercially acceptable product as far as appearance is concerned.

Box B is not a commercially acceptable product.

Box C, although the color on it is light, appears to be a commercially acceptable product.

Now, I am just talking about the appearance of the product in the market. I haven't tasted the product.

Q All right.

Would you go to Box D. Now, Mr. Gilman.

A Box D is a commercially acceptable product.

Box E is not a commerciallly acceptable product.

Box F is a commercially acceptable product.

Q Now could you do the same thing based upon taste, Mr. Gilman.

THE COURT: Do you have a knife?

MR. EINSTEIN: We have a knife and even have a fork. We have all the materials.

A VOICE IN THE AUDIENCE: Counsel, if someone else was going to look at these for color --

MR. EINSTEIN: That's okay.

Q Try not to disturb the fish by tasting it.

A I don't need a knife to taste it. We generally in the trade pull the back fin out.

(Whereupon the witness tastes a portion of fish.)

A This is salty.

Q Is it commercially acceptable?

A Yes.

Q It's Box D?

A No, this is F. It has excess salt for my taste.

(Whereupon the witness tastes another portion

of fish.)

A That is not commercially acceptable.

Q Is that E? Is that Box E, Mr. Gilman?

A Yes.

Q Thank you.

A You know, actually after a while this is all sort of fused into one taste.

Q We do have some water here if that would help you clear your palate.

(Whereupon the witness drinks a cup of water.)

Q Would you try Box D, please.

(Whereupon the witness further tastes a portion of fish.)

A Excellent, very good, commercially acceptable.

(Whereupon the witness tastes another portion of fish.)

A Commercially acceptable.

Q That is which box? A?

A A.

(Whereupon the witness tastes another portion of fish.)

A I can tell by the texture that this is not commercially acceptable.

Q That is Box B?

A B.

Q That is not acceptable?

A No, sir.

Q Okay.

And then the last one I believe would be Box C.

(Whereupon the witness tastes another portion of fish.)

A That's okay.

Q It's okay?

A Yes.

Q Would you take the belly on that box, Box C, rather than the —

MR. MC MORROW: I object. He tasted that specimen the same way he tasted any other specimen. I think we should let it go on that.

THE COURT: I think your point is valid, no matter what the rest of the tests may show, but he may do it.

(The witness tastes the belly of the fish from Box C.)

A It's very salty.

Q Where is the first part you tasted that fish from?

6

Gilman-direct

A The back fin.

Q Is that the deeper part of the fish?

A That's the deepest part of the loin muscle.

Q And the second part I asked you to taste is closer to the surface?

A Yes. The amount of salt in the belly cavity of this fish would make it unacceptable. Of course, there is a different salt penetration in this part of the product and in this part of the product (indicating).

Q Thank you, Mr. Gilman.

Would you resume the witness stand, please.

(The witness resumes the witness stand.)

Q Mr. Gilman, in your capacity as president of Vita Foods, you recall attending a meeting in the spring of 1970 with General Delmore of the Food and Drug Administration?

A I do, sir.

Q Could you tell us what occurred at that meeting, please?

A This was a cooperative meeting between industry, the National Fisheries Institute Industry Technician, the National Fisheries Institute Technical Director and representatives of the Food and Drug Administration.

The purpose of the meeting was to discuss the pending GMP's for the smoked fish industry.

Gilman-direct

Q Can you tell us what was said at that meeting concerning the pending GMP's by representatives of the industry and by General Delmore.

MR. MC MORROW: Your Honor, I object to this line of testimony. Again we are restricted to the administrative record --

THE COURT: Again what?

MR. MC MORROW: This court is restricted in its review to the administrative record. And I think it's improper to hear testimony about meetings held in the spring of 1970. If it's not reflected in the official comments received within the specified period about notice of the propsed rule-making, there ought not to be testimony now, your Honor.

THE COURT: The objection is overruled.

Q You may continue, Mr. Gilman.

A The question is what took place in the meeting?

Q What was said by members of the industry and what was said by General DElmore?

A The members of the industry and their technical advisors strongly objected to various aspects of the GMP. And they voiced their objections and their inability to comply with the pending advisory as the GMP was then referred to. This was an advisory to the industry. And we have some

basic reasons for our objection.

Number one was the fact that there was an inability on the part of industry to reduce product as defined by the GMP. And we voiced our objection. And General Delmore at that time assured us that this was the -- the purpose of this meeting was to get industry's input. And the atmosphere was cordial and cooperative and the Food and Drug Administration was seeking a way in helping the industry produce a product that would be commercially acceptable and yet within safe parameters. And the industry was seeking to work with the Food and Drug Administration.

So they took note of industry's objections and stated that we would be consulted further and changes would be made that would be -- that would create an atmosphere that industry would survive.

MR. EINSTEIN: I have no further questions.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Mr. Gilman, did you know what General Delmore's official capacity within the FDA was?

A He presided -- he was the presiding officer at this particular meeting. What his offi cial title was I do not recall.

Q Now, you stated that you had been president of

Vita Foods -- you had been president of Vita Foods for 15 years?

A Yes, sir.

Q You still have an interest in Vita Foods?

A No, sir.

Q And you are now president of Inter Sea Fisheries?

A Yes, sir.

Q Would you explain again what that company does?

A Yes.

Inter Sea Fisheries is a fish, shellfish and commodities brokerage. We sell commodities of fish and shellfish and various aspects of the fish industry.

Q Do you sell product to Vita Foods?

A No, sir.

Q What sort of people do you sell products to?

A We handle many products. We sell products to wholesalers and processors and manufacturers of various types of product.

Q I take it then the consumption of the end product which you broker has a direct bearing upon your direct business, the more of the product consumed by the public, then the better for your business. Is that correct?

A Yes.

Q So you have an interest in seeing that the public continues to purchase products as it has in the past, whatever those products that you broker may be?

MR. EINSTEIN: Excuse me, your Honor. I don't think there is a question. If there is, I certainly object to it as being argumentative.

THE COURT: I think the point has been covered by the previous question and answer.

Q Mr. Gilman, where do you live?

A New York City.

Q Now, what do you define by a commercially acceptable product in terms of appearance?

A A commercially acceptable product in terms of appearance is a product that is salable in the marketplace according to the customs and the -- of the trade, having an appearance that people are familiar with and will purchase.

Q So would you say one of the key features is familiarity?

A I would say a key feature of making a product commercially acceptable, it has to meet the industry standards as people are used to buying the product.

Q In other words, it goes to the traditional buying practices of the consumer?

A This has a great deal to do with it, sir.

Gilman-cross

Q In your capacity as president of Vita Foods did you ever experiment with marketing of any of the specimens of fish which you characterized as commercially unacceptable by appearance?

A Yes, I have.

Q Would you explain to us how you did that?

A Well, I started my career in the fish business, in the smoked fish business and I have been active in the smoked fish business all of my career. And when we had -- when the situation arose that this time temperature situation first came up, we sought to comply and produce product in accordance with the GMP. And we couldn't produce a product that we could sell.

(continued next page)

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3pm/2

Q Would you please explain to me what attempts you made to sell the products that you did produce with processes that were in compliance with the GMP?

A The attempts that we made?

Q Yes.

A We produced the products -- and I might add this is rather expensive raw material. And we would produce products, pack it and offer it for sale and have it rejected.

Q To whom did you offer it for sale?

A To the distributors and retailers that we did business with.

Q Was this an effort just on the part of Vita Foods or was it a combined effort on the part of other smoked fish processors?

A I am more familiar with what I did with Vita. But in my discussion with others in the trade, other people have told me they tried to do the same thing.

Q But you didn't try and market this product in combination with other smoked fish processors in the community; is that correct?

A We did try to market it in combination? No, we never did anything like that. We sold our product in competition with other processors, not along with them.

Q So a distributor who returns your product would

receive your product and say I can't sell this and then he would send it back to you?

A In some cases he would send it back and in other cases if it would be the distributor picking up he wouldn't take it out, he wouldn't buy it.

Q Is the same distributor able to go to another fish processor and get a product which he deems to be commercially acceptable?

A I would assume so, yes. If he didn't like our product and he went somewhere else he could buy their product, yes.

Q So you didn't get together with the other people in the smoked fish industry and say, "Let us all try to cook this fish at 180 degrees for 30 minutes and offer this product to the distributor and to the consumer"?

A I can answer that best in this manner: There are various methods of smoking this product. In a gravity smokehouse there is not a chance in the world of producing a product at 180 degrees in 30 minutes. There is just no way.

THE COURT: You see, Mr. McMorrow's point is this: that insofar as your testimony goes, you might have been trying to sell products produced under the GMP in competition with products not produced under the GMP, but of familiar appearance. Is that right?

THE WITNESS: That is right, your Honor.

THE COURT: And so the product of familiar appearance would push yours out of the market, right?

THE WITNESS: Well, that's what -- that would have happened if one firm continued to smoke --

THE COURT: Yes, if I understood you.

THE WITNESS: Yes.

THE COURT: So if you tried to push product made under the GMP, you couldn't push it against product not made under the GMP?

THE WITNESS: I couldn't push it at all because --

THE COURT: But it was never in the market, in a market made -- made up wholly of dried whitefish, smoked whitefish, whatever you call it, produced in accordance with GMP standards --

THE WITNESS: No.

THE COURT: -- in gravity ovens.

I think that's what Mr. McMorrow's question was.

So that the one experiment never tried was to withdraw non-compliant fish from the market and see if when non-compliant fish were withdrawn from the market, compliant fish would finally be acceptable as marketable.

Is that true?

MR. MC MORROW: That's right, your Honor.

THE COURT: Would that experiment, since I take it it might have involved some modest toying with the anti-trust laws, was never quite arranged or was it?

THE WITNESS: That was never arranged, no, sir.

THE COURT: And it never happened?

THE WITNESS: It never happened.

May I make a comment on that?

THE COURT: Better not. Better wait and talk it over with counsel first.

MR. EINSTEIN: I am perfectly happy with whatever Mr. Gilman wants to say.

THE COURT: Now he said it. Go ahead.

THE WITNESS: Through our technicians -- I mean we did try to get as much industry technology as we possibly could. And I mean this matter was discussed on an industry basis through the Shuster Operation, that is, the technology, the technical groups that we employed, and through Mr. Sanford and Roy Martin of the National Fisheries Institute, and through the Bureau of Commercial Fisheries. I mean, we as an industry did work collectively in that manner. I mean, it wasn't a question of us just seeking to constantly take each other's customers. And we did collectively through these various agencies, the Bureau that became the National Marine Fisheries Service,

the Shuster Laboratories, and the National Fisheries Institute, we did collectively work and it was the collective judgment of all concerned that we could not produce available product in the market place whether everybody produced it this way or nobody produced it this way. This was so completely foreign to the taste and appearance of what the consuming public purchased.

Q Before I pursue that I'd like to ask you one further question about your attempts to market the product.

I take it that you did not employ any marketing company or any advertising agency to attempt to develop commercially acceptable, of the product which was produced in compliance with the GMP?

A We did.

Q You did?

A Yes, we did.

Q Would you explain what those attempts were?

A Yes. We had an association of smoked fish processors and we had a tag or a sticker on the box indicating we were members of this association of smoked fish processors. Vita Foods individually in various trade advertisements as well as newspaper advertisements did try to give the trade name connotation to smoked fish. And we also had trade advertising as a group some years ago.

Q But did you ever go to the consumer?

THE COURT: To wean him away from the old to the new?

THE WITNESS: Your Honor, there was no way we could produce the new. So we didn't attempt to wean them away to something that would be impossible for us to comply with.

Q So your answer is that you saw no necessity for it then?

A We saw no necessity for doing so. We couldn't produce a product under the GMP that we could sell.

Q You stated you were working in conjunction with the Shuster Labs, the NFI and the Bureau of Commercial Fisheries to try to develop technologies. Is that correct?

A That's correct.

Q Would you tell us, are you in a position to describe to us what efforts were being made by the industry to develop technologies that might enable the industry to comply with GMP's?

A Yes, I can do that.

I myself personally attended meetings at the Bureau in Ann Arbor, Michigan. And there was a -- there were funded experiments employing scientists through the Bureau to see what we could do. This was in conjunction primarily with

chubs at the time, after a problem we had had in the industry. And we worked together. We had a technician or director of technology for the National Fisheries Institute at that time who was Mr. Ted Sanford and he devoted a great deal of his time and effort. And we had various grants that were -- I don't specifically remember them because we are going back many years, but we had various scientists working on different items in conjunction with technology in the industry.

Q Are you speaking primarily of the work that was being done by the Bureau of Commercial Fisheries?

A I am speaking primarily of the work that was done by the Bureau of Commercial Fisheries and the National Fisheries Institute and my ex-firm and the smoked fish group here in New York. It was a cooperative effort. It wasn't done by just one group. We all worked together on it.

Q Were they working together to develop alternate parameters with respect to time and temperature for cooking or were they working to develop technologies which would help them comply with the GMP?

A I would say it was a combination of both. I think we were working to produce a commercially acceptable product and we were also working to produce a safer product as we could. So there were various balances of salt and temperatures, blinds and temperatures, which are the two ways

of making the product safe and palatable.

Q In other words, at least a portion or part of your efforts which were being expended by the industry organization were towards scientific research or towards developing alternate parameters for the GMP?

A I would say this led up to that, yes.

Q Do you recall what efforts were being made to -- actual specific efforts which were being made to develop technologies?

A I can tell you the efforts that were made, yes. We -- some firms went into the more sophisticated type of smokehouses where they could have time and temperature controls, I mean better or more scientific recording methods of producing products.

Q Were you aware of -- I presume that if you were in Ann Arbor you were aware of the work being done there by the commercial fisheries -- I'm sorry, by the Bureau of Commercial Fisheries?

A I was aware of some of the work that was being done I attended some of the work there, yes.

Q Were you aware of the fact that the Bureau of Commercial Fisheries was of the opinion that, that at least with respect to the processing of chubs that it was possible to produce a commercially acceptable product within the GMP's?

MR. EINSTEIN: I object, your Honor, that assumes a fact that is not in evidence.

THE COURT: I couldn't hear the question. Would you please read it for me, Mr. Rapaport?

(The court reporter reads defendant question.)

A I was aware of it, but in producing chubs we were permitted to produce chubs at 160 degrees for 30 minutes with nitrates, whereas with whitefish the GMP is 180 degrees.

Q But is it not true that the research that was being done also established that chubs could be cooked at 180 degrees with sophisticated technology?

A To my knowledge that is not correct, sir.

MR. MC MORROW: No further questions.

(Continued on next page)

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MR. MC MORROW: I have no further questions.

MR. EINSTEIN: Just one question.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Does the Intersea Fisheries Company deal in whitefish?

A No, we don't sell whitefish.

MR. EINSTEIN: Thank you. You may step down.

(Witness excused.)

MR. EINSTEIN: We call Mr. Saul Sabar.

S A U L S A B A R , having been called as a witness on behalf of the defendant, having been first duly sworn by the Clerk of the Court, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Sabar, what is your occupation?

A I am in the food business.

Q And what kind of food do you sell, are you a seller of foods?

A Retailer, retailer in foods.

Q Among the foods that you retail, are whitefish included?

A Yes.

2 Sabar-direct

Q And approximately how long have you been a retailer of foods?

A I have been in the business since 1951.

Q And approximately how many pounds of whitefish do you sell per week?

A We will sell between 500 and -- between 500 and 700 pounds a week.

Q And during the course of your years in the business and based upon the sales that you make weekly, have you come to have an awareness of what is or is not a product which your consumers will accept?

A Of course.

Q Mr. Sabar, I am going to ask you to step down to counsel table and you will see there are six boxes of fish marked A through F. Let me ask you first, have you ever seen these fish or tasted them before this occasion?

A These particular fish?

Q These particular fish?

A No.

Q In fact, we have never talked until just this moment?

A Yes.

Q I'm going to ask you to step down, examine the fish, both visibly and by taste and do whatever you think is

3 Sabar-direct

necessary and tell us which fish are commercially acceptable?

(Witness leaves witness stand.)

MR. MC MORROW: I wish to state an objection to this testimony and to this experiment.

MR. EINSTEIN: Will you start with the box marked A?

Q I would appreciate it if you took a look at the tag, Mr. Sabar?

A We would not -- should I make a comment?

Q Tell me whether the fish in box A are commercially acceptable in your business?

A No, these would not be acceptable.

Q For what reason?

A They are too hard, too dry.

Q Would you go to box B, please?

A This is even worse than the first one.

Q What is the problem with those?

A They are too dry, they're overcooked. Terrible.

Q Would you go to box C, please?

MR. MC MORROW: Mr. Sabar, you're supposed to comment?

THE WITNESS: Too salty. Terrible. I mean these are terrible.

THE COURT: What did you say about C?

THE WITNESS: They're just excessively salty. Besides that, they're too hard and overcooked. They're just too salty for our type of business. We wouldn't sell them. We wouldn't consider selling them.

Q Would you go to the box marked D. If you need some water?

A I will need it when I am finished. These are worse.

Q In what respect?

A They are terribly salty. The amount of salt is just not acceptable.

THE COURT: What?

THE WITNESS: The amount of salt is not acceptable. They are too salty.

Q Go to box E?

A And these are hard -- these are hard, they're just not saleable. They're hard and they're dry.

Q Would you go to the box marked E, please?

A This is E?

Q Yes, sir.

A These are even worse.

Q In what respect?

A I mean they're like little bricks. You know,

terribly salty and they're just so dry and so hard. Seriously, it's not even acceptable or edible product. It's not something that would be eaten by anybody.

Q Would you examine box F and let us have your opinion on the fish in that box?

A The color is better on these. But these are also terribly salty. They are too salty for normal people and too dry. They are too hard and dry. These are not -- I can't -- I don't think any retailer could sell these.

MR. EINSTEIN: Let me offer you a glass of water and you can resume the witness stand.

(Witness resumes witness stand.)

MR. EINSTEIN: You may inquire, Mr. McMorrow.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q I take it, Mr. Sabar, you couldn't sell any of these?

A I wouldn't handle it in my store, any of those products.

MR. MC MORROW: I have no questions.

MR. EINSTEIN: Thank you.

(Witness excused.)

MR. EINSTEIN: We call now Mr. Arthur Cutler.

(Continued next page.)

ARTHUR CUTLER, having been called as a witness on behalf of the defendant, having been first duly sworn by the Clerk of the Court, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Cutler, what is your business or occupation?

A I own Murray's Sturgeon Shop in Manhattan.

Q And is Murray's Sturgeon Shop a retail shop which sells hot smoked whitefish?

A Yes, it is.

Q And how long have you been connected with the business of Murray's Sturgeon Shop?

A A year and ten months.

Q Have you had any prior experience in the sale of hot smoked whitefish?

A Yes, off and or throughout my whole life.

Q For how many years have you had such experience?

A Twenty-four years.

Q And approximately how many pounds of hot smoked whitefish does Murray's Sturgeon Shop sell each week?

A Around 150 pounds.

Q Based upon the business in your shop and your years of experience, are you familiar with what is or is not

saleable or commercially acceptable products to be consumed by the public?

A Yes.

Q And have you ever, prior to today, seen or examined those particular fish that are on counsel table?

A No.

Q I will ask you then to step down and to examine these fish and tell us which ones are or are not commercially acceptable or could be sold in your shop?

THE COURT: Could counsel come up tothe side bar? Mr. Sabar, please stay there.

(The following occurred at the side bar.)

THE COURT: I was wondering if this time you might start with D, E, F. The palate gets weary?

MR. MC MORROW: And go back to A?

THE COURT: Let us change the order.

MR. MC MORROW: And I would like to state while I am here we object to t his testimony for the reason stated before. I object to the experiment and also I want to reiterate again for the record that the administrative record indicates that the FDA, in promulgating the regulations, gave consideration to this and took into effect taste tests and pilot products and production in commercial smoked fish

processors factories, monitored by the FDA in promulgating the regulations.

(The following occurred in open Court.)

BY MR. EINSTEIN:

Q Mr. Cutler, I appreciate it if you would hold off on the fish for a moment?

(The following occurred at side bar.)

MR. MC MORROW: This is a matter which has been given consideration by the agency.

THE COURT: This is all taken subject to your objection and my rulings, those among other reasons.

(The following occurred in open Court.)

BY MR. EINSTEIN:

Q Mr. Cutler, will you look first at the box marked D, this one here and tell us whether those fish are commercially acceptable or saleable, both by visual inspection and by sight.

THE COURT: And by what?

MR. EINSTEIN: I'm sorry, by taste. It must be late in the day, your Honor. Excuse me.

A There is no taste, not bad.

THE COURT: What did you say?

THE WITNESS: They're not bad. I wouldn't say the finest quality. But I think they're probably

acceptable.

Q Go to the next box, E, please?

A By sight they are horrendous and would not be sold in my store at all. Terrible taste.

Q Would you go to box F, please?

A This is an extremely firm fish. Doesn't have bad appearance. I wouldn't sell it in my store.

THE COURT: What?

THE WITNESS: I wouldn't sell it in my store, both for appearance and taste.

Q What is wrong with the taste?

A It's a very hard fish and somewhat salty.

Q Would you go now, sir, to box A over here?

A WEll, the appearance is somewhat better in this box, what is this box?

Q Box A.

A Box A, it is a dry fish and again it would not be acceptable.

Q Would you go to Box B now?

A Not acceptable from appearance, certainly. This piece of fish couldn't even enter my store. I wouldn't even taste it because just by appearance alone it would be rejected.

Q Would you move finally to box C?

10 Cutler-direct

A Rejected both on appearance and on taste. Very salty, hard, firm, frozen, watery. N.G.

Q No good?

A No good.

Q You can resume the stand, please.

(Witness resumes witness stand.)

MR. EINSTEIN: Your witness.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Mr. Cutler, of the specimens that you said you would not let into your store, have you ever attempted to sell fish that is like any of these specimens which are here before us?

A From time to time a supplier would send in a piece of fish that might look and taste like that and it is immediately rejected.

Q By you?

A By me or anybody that worked for me.

Q Beg your pardon?

A By me or anybody that works for me.

Q I see. Have you attempted to sell fish such as that which you found unacceptable here to the public at all?

A For the past couple of months, fish have been -- they have been coming in extremely salty, extremely dry and

poor saleable appearance. We have met tremendous consumer resistance. Our whitefish sales are down dramatically. Even though we do a very big business with Nova Scotia Food Products, we have curtailed our whitefish purchases from them.

Q I take it that one of the comments which you gave us was a lot of fish are too hard. If the moisture were improved in the fish, might that improve its acceptability?

A Definitely. A whitefish that is moist and not salty, and sweet, is a perfect whitefish, yes. If you can get -- meet all those requirements, then you will sell a good quality piece of merchandise.

Q But moisture is one of the key factors, is it not, it is one of them?

A Moisture, yes.

MR. MC MORROW: Thank you.

MR. EINSTEIN: No questions.

(Witness excused.)

MR. EINSTEIN: Might I suggest a recess, your Honor, for what I think is called in the industry as sanitizing. Unless the Government wishes to take care, custody or control of these fish, we intend to discard them?

MR. MC MORROW: Your Honor, I wouldn't like them

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in my office, no. Let Mr. Einstein take care of them.

(Short recess.)

(Continued next page.)

MR. EINSTEIN: YOur Honor, Mr. Morey will conduct the examination of the next witness.

MR. MOREY: Mr. Harvey Oxenberg.

H A R V E Y O X E N B E R G, called as a witness, being duly sworn by the Clerk of the Court, testified as follows:

DIRECT EXAMINATION

BY MR. MOREY:

Q Mr. Oxenberg, where do you live?

A Miami, Florida.

Q What business are you in?

A Smoke fish processing business.

Q What is the name of your company?

A Florida Smoked Fish Company.

Q What is your position in that company?

A My corporate position is treasurer of the corporation.

Q How long has Florida Smoked Fish been in business?

A The company was formed in 1954. But I am a third generation in the smoked fish business. My father and grandfather before him were in business in New York from approximately since 1920.

Q Howmany pounds of whitefish do you smoke a week?

A Approximately five thousand.

Q What would your weekly sales volume from hot smoked whitefish be?

A Something in the area of $8,000.

Q How many people are employed by Florida Smoked Fish?

A Between forty and forty-five.

Q Has anyone ever complained to you about botulism illness from hot-smoke whitefish prepared by Florida Smoked Fish Company?

MR. MC MORROW: I wish to object to the entire line of testimony for the reason stated before. I believe it's irrelevant to the case in hand and is beyond the scope of this Court's review.

THE COURT: The testimony will be received subject to the same limitation.

THE WITNESS: No.

THE COURT: Under the same ruling.

MR. MOREY: The record reflects the answer to the question is "No."

Q Mr. Oxenberg, what kind of ovens do you employ at Florida Smoked Fish in smoking whitefish?

A We have electronic ovens.

Q How long have you had these ovens?

A Almost four years.

Q These are not experimental?

A No, they are not experimental.

Q T hey are the only kind you use in the processing of this type fish?

A That's right.

Q W hat happens when you prepare hot-smoke whitefish in these ovens at internal temperatures of 180 degrees Fahrenheit?

A Well, you find that the fish -- the skin of the fish is blistering, discoloring, becomes darker than what is normally acceptable at the market place. The bellies open up. And you will find that they split inside the belly cavity.

Q All right. Mr. Oxenberg, do your ovens allow you to control humidity?

A Yes.

Q Have you attempted to process hot-smoked whitefish with controlled humidity? And if so, what results did you make?

A We have -- we have done extensive work on that. We find the only thing that the addition or the injection of humidity generated by a steam boiler is that the smoke becomes more intensified and that the color of the fish becomes

darker than it normally would if the steam were not injected into the oven.

Q So if a fish were smoked, using this method of control to 180 degrees Fahrenheit, what would be the result?

A Not favorable. They would -- as I mentioned earlier, they would -- the steam causes the smoke to penetrate the fish even more than the -- when the steam is not injected. Therefore, the fish would be darker and unacceptable.

Q Do your ovens allow the use of steam injection?

A Yes.

Q Have you experimented with that?

A I have alluded to that earlier. That's the same process.

Q That's the same as the humidity? Not two separate --

A Correct. The same.

Q Mr. Oxenberg, have you ever brined fish to the extent that you achieved a level of 3.5 per cent water phase salt in loin muscle?

A Yes, we have.

Q What is your experience as to the marketability of these fish?

A They are not marketable in the area in which we operate.

If I may expound on that a little bit.

We process in an area in South Florida where there are a number of retirees, people over the age of 65 who are very cognizant of their salt intake. And each time that we attempt to attain a 3-1 /2 per cent internal salt content, we get numerous complaints from customers and the consumer.

Q All right. What would be the effect on your business if you had to prepare all of your hot-smoked whitefish at 180 degrees Fahrenheit internal temperature?

A It would certainly reduce the sale of smoked whitefish.

THE COURT: What?

THE WITNESS: It would reduce the sale of smoked whitefish.

Q What would the effect be if you had to prepare all of your whitefish with five per cent salt?

A I don't think any whitefish would be sold with five per cent salt.

Q Mr. Oxenberg, are you a member of the National Fisheries Institute?

A Yes, I am.

Q Do you hold an official position with the National Fisheries Institute?

A Yes, I do.

Q What is that position?

A I am chairman of the smoked fish committee.

Q Will you very briefly describe the National Fisheries Institute in general?

A NFI is a national trade association consisting of some 625 members who are in the business of either producing, catching, marketing, processing all types of seafood products, consisting probably of the largest percentage of the seafood produced in this country and sold.

Q All right. Now, referring specifically to NFI Smoked Fish Committee, could you describe that committee, the nature of its members and its activities?

A NFI Smoked Fish Committee consists of various smoked fish processors arou- d the country. I would guess rperesenting the lion's share of the smoked fish industry. And its function is to discuss and -- to discuss industry matters concerning the smoked fish industry.

Q Was the smoked fish committ ee involved in the -- for want of a better word -- negotiations with the Food and Drug Administration concerning the proposed smoked fish GMP regulations?

A Yes, they were.

Q And, to your knowledge, was NFI, in particular the Smoked Fish Committee, given any legal advice as to the effect of those regulations which they were promulgating in November, 1970?

MR. MC MORROW: Your Honor, I object to this line of testimony. I don't see what relevancy legal advice that they -- that other members of the industry, other than the defendant, or even the industry itself may have received at that time, that it has any bearing on this proceeding.

THE COURT: Well, neither do I. But I better receive it in case someone else holds that it is relevant.

A Yes. We received legal advice from the firm of Covington & Burling at the time that you were a member, and we were advised --when I say "we," I mean the National Fisheries Institute and the Smoked Fish Committee -- were advised that the GMP's were guidelines to be followed and that they could be pursued in a court of law if it were necessary. But that they were only guidelines.

Q Mr. Oxenberg, has the National Fisheries Institute been involved in the sponsorship of any research regarding smoked white fish?

A Yes, they have.

Q Would you describe the role of NFI as to that research?

A Well, initially, in respect to the research program, the smoked fish processors, the members of the Smoked Fish Committee, raised funds for the purpose of sponsoring research. Subsequent to the raising of funds from the smoked fish processors themselves, NFI has committed certain funds -- funds that have been generated through all of their members to this research.

Q Mr. Oxenberg, has the National Fisheries Institute done any work in connection with educating the consumer as to the proper handling and consumption of whitefish?

A Yes, they have.

Q What was the nature of that?

A The nature of it was to try to present to the public in the manner of a brochure that will be distributed to the retail outlets throughout the country concerning the handling and storage of smoked fish products.

MR. MC MORROW: Your Honor, again I must object to this line of testimony. I believe that it is going far beyond the issue that should be before this Court at this time.

THE COURT: Well, I don't quite see where it

fits in, Mr. Morey.

MR. MOREY: Well, your Honor, part of the scientific case that is involved here, I believe, will indicate that the danger, if there is any, from these products arises only when there is abuse of handling. And this pamphlet, again, as I understand it, is designed to educate the consumer so as to eliminate or minimize that possibility. So it would be connected to later scientific testimony.

MR. MC MORROW: But your, these are facts which were already taken into account by the agency. Furthermore, if I understand the Court's ruling yesterday correctly, this Court has ruled that it will not permit the scientific evidence to be introduced. I believe you said that the defendant could make an offer of proof, but you would not receive scientific testimony. And I would think that that would certainly minimize or eliminate the need for this sort of testimony at this time. Indeed, it would make this testimony irrelevant.

THE COURT: It would seem so to me, Mr. Morey. I really think this is much farther away from the issue.

MR. MOREY: All right.

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BY MR. MOREY:

Q Mr. Oxenberg, have you been involved in recent negotiations with the Food and Drug Administration concerning the enforcement of the smoked fish GMP regulations?

MR. MC MORROW: Your Honor, I object to this line of testimony as well. Again, this has no bearing on the issue before the Court. Mr. Oxenberg is not the defendant here.

THE COURT: It's hard to see what it has to do with our case.

MR. MOREY: Your Honor, what I am leading up to here is a meeting of May 29, 1975 between members of the industry and the Food and Drug Administration in which this problem was discussed, and in which it was agreed by the FDA that a task force would be set up for dealing with this problem. That task force has never been set up and we recently received a letter in which the FDA said it would no longer participate.

I think this is at least relevant to the equitable position that is part of this case.

MR. MC MORROW: Your Honor, I believe that this is quite inappropriate for two reasons: One, what happened in May of 1975 has no bearing on the

case before this Court. And as such, the issue of the task force I believe that takes us into negotiations which at least in part were -- you know, related to negotiations or discussions between the agency and the industry was transpired after this case was brought. And I think it is very inappropriate to make reference to them at this point.

THE COURT: This case was started much after that.

MR. MC MORROW: That's true. But he's talking about with respect to at least the --you know, the pursuing of the issue of the task force. He's talking about a meeting in 1975.

THE COURT: It seems to me it's quite beside the point anyway. I think it must be excluded, Mr. Morey.

MR. MOREY: Your Honor, I think that the relevancy would be to what Mr. Sklar's reasonable expectation would be. Mr. Sklar was well aware that all this was going on and that attempts were being made, and that at that time we thought we had an agreement with the Food and Drug Administration as to a method for working this out which would avoid the type of action

we are involved in right now. I think it's an equitable matter that is relevant.

THE COURT: No. I will not accept it.

(Continued on next page.)

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Q Mr. Oxenberg, have you collected statistics as to the general size of the smoked fish -- smoked white fish industry in this country?

A Yes, I have.

Q Could you indicate what they are?

A There are 32 plants in the United States producing smoked white fish, employing approximately 939 individuals, producing somewhere in the area of two and three quarter pounds of white fish with a retail value of approximately eight million dollars.

THE COURT: A year?

THE WITNESS: Yes.

Q Mr. Oxenberg, have you made inquiry as to whether there have been any incidents of botulism illness from white fish since 1963?

A Yes.

Q And what have you discovered?

A There have been none.

Q What is the source of your information?

A National Marine Fishery Service.

Q Finally, Mr. Oxenberg, could you briefly tell us what the interest of the National Fisheries Institute is in this litigation and why it chose to participate as it did?

A Well, as I mentioned before, the National Fish-

eries Institute represents or includes approximately 625 seafood processors, brokers, manufacturers, producers, boat owners, and a substantial portion of these people are involved in the -- either a supply or the processing of smoked fish products, and, therefore, they deemed it appropriate by a unanimous vote of their board of directors to intervene in this case.

Q I thought I asked you this, but what is the quantity of smoked fish that you sell per week?

A My firm?

Q Yes.

A Approximately five thousand pounds.

MR. MOREY: Thank you. You may enquire.

MR. MC MORROW: Your Honor, Mr. Friede will conduct the cross examination of this witness.

CROSS EXAMINATION BY

MR. FRIEDE:

Q Mr. Oxenberg, your testified that you market your product in the south Florida area?

A Primarily, yes.

Q And could you -- Did you testify that there are several retirees or a preponderance of retirees in that area?

A I said there are some, yes.

Q And that these people comprise a large section

of your market?

A Correct.

Q Do you have any idea of the locations where most of the purchasers of your white fish resided at the time prior to their retirement?

A No.

Q Would you say that a significant number of the people who purchased your white fish in the south Florida area may be from the New York, New Jersey or northeastern area of the country?

A I don't know.

Q Is there a large Jewish population in Florida in the Miami Beach area?

A What's large?

THE COURT: Either in numbers or in percentage of population. If it's large in terms of the size of New York City, then the --

THE WITNESS: There is a substantial Jewish population.

Q Have you talked to several people -- How many people have you talked to, to determne the reason why they like or do not like their fish to have a certain salt content?

A How many?

Q How many?

A I don't know. I don't have a number.

Q You testified that there were numerous people who are consumers of smoked white fish and who do not have -- do not like to have very much salt because of health reasons. How many people have you spoken to?

A Well, generally, the complaints originate from the customer that we sell to, who is then selling to the consumer.

Q In other words, this was not directly communicated to you from the person making the observation?

A No, I didn't say that. I said that primarily the complaints that we receive are from the customers that we serve. But there are occasions when we will receive telephone calls from the consuming public --

Q Now --

A -- saying, --

Q Now --

A I am sorry.

Q On the particular fish that you receive complaints about as to their salt content, have you ever analyzed a particular fish to determine its salt content as to one of the ones for which you had received a complaint?

A No.

Q Thank you.

Now, you testified that the -- Your use of the experimental -- Your use of a steam injection oven created a darker color skin; is that correct?

A Yes, I did.

Q What kind of a steam injection oven are you using?

A Alkar.

Q Alkar. Is that the same Alkar Rasputin steam injection that is used by Vita?

A Correct.

Q Now, would you explain to me the process that is used to determine the amount of humidity that goes into that oven at any particular time?

A It's identical to Dr. Bierman's testimony. It's a -- You have to figure the wet bulb temperature and the dry bulb temperature. From that you can determine the relative humidity within the chamber.

Q For example, at the start of smoking the wet bulb temperature, it would be -- The dry bulb temperature --

A I am not one hundred per cent familiar with the exact computation.

Q I'm sorry. The dry bulb temperature is what the -- the start of smoking, do you have any idea?

A Ninety degrees.

Q At that point, what would be the wet bulb

temperature?

A I don't know.

Q Isn't it true that in determining the relative humidity within the oven, that the computation is based on the difference in value between the dry and wet bulb temperature? Is that true?

THE COURT: I think it's a ratio.

THE WITNESS: A ratio between the wet bulb and the dry bulb.

Q Is it true that the lower the difference between the dry bulb and the wet bulb temperatures, the greater the humidity in the oven is?

A I don't know that.

Q How are you then determining -- How do you determine the amount of relative humidity which is injected into the oven at any moment?

A Somebody from my firm knows that information.

Q Who is that?

A Our smoker.

Q Have you not discussed that matter with him as to how he is doing it?

A Sure. but I am not directly familiar with the exact relationship between wet bulb and dry bulb temperatures.

Q Who is -- Who did he receive this training from?

A To begin with, I was more familiar with the --

Q You were --

A I was more familiar then than I am right now today. I don't know the exact thing -- the exact figures. I don't have them in hand.

(continued next page)

Q Did you send the smokers who are operating your ovens to a food technologist who is familiar with thermal heat transfer ovens?

A Well, the employees that we have working on the smoking equipment are trained by the manufacturers representatives and they primarily receive their training from them.

Q Where are the manufacturers representatives for your area located?

A Well, the manufacturers are located in Iowa.

Q Where is the representative?

A Where is he?

Q Do you have one -- is there one in the South Florida area or is this in North Carolina?

A That's correct.

Q And have you been --

A But that's a sales representative. I believe you might be referring to -- that is not a technical representative. I'm not sure where this person lives or these people live.

Q But you believe that your smokers had training from these people on how to accurately and appropriately operate the controls on the Alkar rasmussen oven?

A With respect to the dry volt and wet volt, yes.

Q Would you be able to tell me at which point the

humidity is injected into the Alkar oven; for example, if the relative humidity in the oven was 20 degrees -- 20 per cent at the start of the smoking operation, at which point in time would you inject the humidity into the oven?

A I don't know that.

Q Well, isn't it true that the only point in time when relative humidity would be injected into the oven is when the setting on the outside of the oven -- when the relative humidity in the oven is reached --

MR. FRIEDE: This something I am not familiar with.

Q In any event you are not able to fully describe the way the humidity control oven works and your smokers only technical training was from representatives of the company; is that correct?

A Correct.

Q Now you suggested that the only thing that the injection of humidity does, that it intensifies the smoke within the oven and that the color of the fish becomes darker?

A I don't think I said intensifies the smoke from within the oven. What it does, it intensifies the color that the fish will absorb.

THE COURT: Absorbtion.

THE WITNESS: The absorbtion.

Q Do you not have a separate smoke generating device which feeds the smoke into the oven during the smoking process?

A Yes, we do.

Q In other words, you're not sticking wood shavings in the oven, is that correct?

A No.

Q Now prior to the time that you began utilizing the system of injection oven, what type of oven were you using?

A Gravity.

Q Now in the gravity ovens was one of the problems that you had when you tried to reach 180 degrees, 30 minutes, that you would encounter some weight loss in the fish, these are weight losses when you go up to certain temperatures?

A There is a weight loss when you smoke fish, yes.

Q Could you give us the average weight loss at a particular time temperature?

A No, I could not.

Q Would it be true that there would be a loss of shrinkage in the fish if it were cooked in a steam injection oven for 180 degrees at 30 minutes as opposed to being cooked in the gravity oven for 180 degrees, 30 minutes?

A I do not know that for a fact.

Q Now, could you tell me something about the manner

in which you brine the fish; for example, how long your fish are kept in brine, your whitefish?

A Twenty four hours.

Q Now, during that period of time do you agitate the brine solution?

A Manually.

Q You have no centrifugal pumps on the brine tanks who periodically agitate them?

A No.

Q During that 24 hour period that the fish are in the brine solution, is there someone at the plant during that entire time?

A No.

Q So, therefore, there are certain intervals in time when there is no agitation taking place, is that correct?

A Yes.

Q Now, in determining the -- once you have placed the fish into the brine, do you then periodically add salt or is the salt level at the original level --

A We do not add salt.

Q You do not add salt. Now, have you sought the advice of any expert, particularly any technologist on thermal heat transfer ovens regarding the use of this steam injection oven, other than the manufacturers representative?

A Can you repeat that question?

Q Other than from the representative of the Alkar Rasmussen Company have you personally or your smokers sought technological advice from engineers on the use of this steam injection?

A That is a lot of question. We had sought technical advice, technological advice.

Q You testified that the National Fisheries Institute has recently, has given a grant of money to Dr. Eklund to conduct research into the smoked fish problem; is that correct?

A No, it's not exactly correct.

Q Would you tell me what has happened?

A They have determined that they were going to put money into the smoked fish research fund which was the fund that was created by the smoked fish community.

Q When was that fund created?

A I'm not sure of the exact date.

Q Isn't it true that the funding of Dr. Eklund's research began only in 1975?

A From NFI?

Q Correct.

A That's correct.

Q And that NFI did not -- let me rephrase that

question:

Has NFI ever attempted to contribute funds to develop new technology instead of altering the process, a new technology that would be capable of complying with the GMP's?

A Repeat the question?

Q Has NFI, in funding the research, attempted to fund research directed toward refinement of existing technology or developing new technology capable of complying with the GMP's?

A I can't distinguish between them, really.

Q Have they funded research which would -- whose aim was to refine existing technology so that they could comply with the GMP's?

A No, I don't think that is accurate.

Q So they have never funded such research, is that correct, is that what you are saying?

A No. I'm not sure that the funding of the current research is the way you characterize it.

Q Well, is the funding of the current research designed to develop alternative processing parameters?

A Yes.

MR. FRIEDE: Thank you. No further questions, your Honor.

REDIRECT EXAMINATION

BY MR. MOREY:

Q Mr. Oxenberg, regardless of whether you now know exactly about wet volts or dry volts, has your firm not made an attempt for four years to meet the GMP's on the electronic ovens?

A Yes, we have.

Q Have not those attempts been unsuccessful?

A They have been unsuccessful.

Q Now, as to this research fund of the NFI, was this created at the suggestion of the Food and Drug Administration?

A Yes.

MR. MOREY: Thank you.

RECROSS EXAMINATION

BY MR. FRIEDE:

Q You just testified that you attempted for four years to meet the requirements of the GMP's in your new equipment. Have you consulted with a technologist, just to reiterate, have you consulted a food technologist expert on thermal heat transfer in an attempt to use your ovens to comply with the GMP's?

A Repeat that question?

Q Other than your consultation with the representatives of the Alcar Rasmussen oven, have you consulted or retained

a technician, expert, in thermal heat transfer to help your company in learning how to operate those machines properly so you could comply with the GMP's?

A The two people that we would normally consult on such matters would be the technical directors of National Fisheries Institute and the Association of Smokers and Processors.

Q The answer to my question is no then, other than those two people?

A The answer to the question is yes.

Q Did you ask them specifically about making available to you the expertise necessary to utilize your ovens properly?

A I'm not sure that information is available.

MR. FRIEDE: Thank you very much.

MR. MOREY: No further questions.

(Witness excused.)

THE COURT: We will adjourn now to 10:00 o'clock tomorrow morning.

(Whereupon the Court adjourned until 10:00 o'clock a.m. on May 19, 1976.)

* * *

I N D E X

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
JOSEPH BROWNSTEIN	221		236	
CONRAD SPITZ	237	241		
STANLEY SUTTENBERG	244			
MORTIMER KORCHIN	252			
DAVID SKLAR	262		328	
DOCTOR BIERMAN			332/346	338
AARON GILMAN	348	357		
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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

----------x

UNITED STATES OF AMERICA, :

-against- : 76-C-647

NOVA SCOTIA FOOD PRODUCTS, :

Defendant, :

----------x

United States Courthouse
Brooklyn, New York

May 19, 1976
10:00 o'clock A.M.

B e f o r e :

HONORABLE JOHN F. DOOLING, JR., U.S.D.J.

JOSEPH BARBELLA
OFFICIAL COURT REPORTER

Appearances:

DAVID G. TRAGER, ESQ.
United STates Attorney
for the Eastern District of New York

BY: DAVID MC MORROW, ESQ.
Assistant U.S. Attorney

-and-

ARNOLD FRIED, ESQ.
FORREST T. PATTERSON, ESQ.
Office of Chief Counsel, Food & Drug Admin.

JOSEPH H. EINSTEIN, ESQ.
Attorney for Defendant

RICHARD S. MOREY, ESQ.
Attorney for Intervenor
National Fisheries Institute, Inc.

/lJBhb

MR. MOREY: Your Honor, I would like to re-call Mr. Suttenberg.

S T A N L E Y S U T T E N B E R G , having previously been duly sworn, testified further as follows:

REDIRECT EXAMINATION

BY MR. MOREY:

Q Mr. Suttenberg, you are still under oath.

Mr. Suttenberg, there have been discussions during the testimony, particularly the cross-examination yesterday, that if everyone in the industry shipped it from the familiar product to a different product all at the same time, that the consumer might accept this new product.

Mr. Suttenberg, are you aware of any situation where something of this nature had to be done by the industry?

A Yes, I am aware.

Q Would you please describe that situation and what the attitude of the consumer was toward the new product.

A Well, just on the whitefish, if it was -- if you would all smoke it the same way --

Q Mr. Suttenberg, what product was it that had to be changed?

A Chubs.

Q What change was made?

A Well, we were smoking, I would estimate in the New York area -- New York metropolitan area, about 125,000

pounds of chubs a week, going back to about eight to ten years ago. When Lake Michigan had some problem with -- some people decided we could use the chubs from Lake Michigan. And so consequently we had to change from Lake Huron and Lake Superior. Now, these chubs are much leaner, much drier and darker than the chubs that people were used to eating from Lake Michigan. And today, after seven or eight or ten years, we are smoking maybe 10, 15 percent in the metropolitan area of the amount we smoked eight to ten years ago. In other words, the consumer never accepted this product, this type of chub. And my estimation is the same thing would happen with the whitefish if we would all cook it on the same -- the same 180 degrees. But the people would not accept it as they did with the chubs which they didn't accept.

Q O.K. This was a situation where the old accepable chub product was all drawn at once?

A From Lake Michigan, yes. And we had to switch to Lake Huron and Lake Superior chubs which are not as fat. They are much leaner, much drier type of fish. And when it was placed on the counter, the people just walked away. And this has been the history of eight to ten years that this has been going on, and where we smoked today, maybe 15 percent in the --

Q And they still haven't accepted it?

A No, they haven't. We more or less forced the customer to take a few pounds, to keep the fisherman going so they should not close up entirely.

MR. MOREY: All right, you may inquire.

RECROSS EXAMINATION

BY MR. MC MORROW:

Q Mr. Suttenberg, did the entire smoked fish industry switch from Lake Michigan to Lake Superior chubs?

A Well, I will have to discuss the New York metropolitan area, which I would approximate would be about 15 percent of the industry in the United States.

Q Did the entire industry switch to low sort of chubs?

A Yes. Because they closed Lake Michigan.

Q Did you get any chubs from any other source?

A Lake Huron and Lake Superior.

Q The same sort of chubs?

A They are called chubs, but they are much leaner, much darker and much drier.

Q Lake Huron chubs are the same as the Lake Superior chubs?

A Yes. Approximately the same.

Q What time temperature parameters were you cooking this new variety of chub?

A The guidelines that the GMP -- it was 160 degrees with nitrate.

Q I beg your pardon?

A 160 degrees with nitrate.

Q But you were not cooking these chubs at 180 degrees for 30 minutes?

A No.

MR. MC MORROW: I have no questions.

MR. MOREY: No further questions.

(Witness excused.)

MR. EINSTEIN: The defendant re-calls Dr. George Bierman.

D R . G E O R G E B I E R M A N , having been previously duly sworn, testified further as follows:

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Bierman, you remain under oath.

Dr. Bierman, do you know of any experts on the thermal transfer of heat with respect to whitefish?

A I know that some work has been done at the University at Georgia on smoking and processing of mackerel. I am not aware of anybody doing any work in whitefish. And I am not familiar with any other people in the thermal transfer area with respect to fish products.

MR. MC MORROW: Your Honor, I must object to this testimony to the extent that Mr. Bierman is attempting to offer expert testimony on the scientific validity of the regulation.

THE COURT: No. The question was asked whether anyone had sought to consult an expert on heat transfer in fish. He says the effect -- as far as he knows, there isn't any expert that could have consulted.

MR. EINSTEIN: I will next ask that eight photographs be marked for identification, please.

They bear on the -- on the back just for reference, numbers 16, 27, 30, 31, 44, 48 and 50.

THE CLERK: Marked for Identification as Defendant's Exhibit G through M.

Q Dr. Bierman, I show you a photograph which has been marked as Defendant's Exhibit G for Identification. Can you tell us what it is and the circumstances under which it was made?

A Yes. This is a photograph of whitefish hung on sticks, on trees, in an electronic oven in preparation for drying and smoking.

Q At what plant?

A Vita Food plant.

Q This photograph was taken in your presence?

A Yes.

Q And it illustrates the type of electronic oven utilized by Vita and the manner in which the fish are hung in the electronic oven?

A That is correct.

MR. EINSTEIN: I offer this in evidence.

MR. MC MORROW: Your Honor, I must object because I don't object what the relevancy of this is.

What is it attempting to show?

MR. EINSTEIN: I think we are trying to get to your Honor some guidance as to how these machines operate, how the fish are hung, and we will be introducing further photographs to show the effect of smoking and various heating procedures both in the electronic oven and the gravity ovens. That is the purpose of it.

MR. MC MORROW: Wasn't that one of the purposes of yesterday's demonstration?

MR. EINSTEIN: I think that on the theory that a picture is worth a thousand words, we think the photographs are important to the record.

THE COURT: Well, since we have them, let's make what use we have of them that we can.

THE CLERK: So marked Defendant's Exhibit G in

Evidence.

THE COURT: You notice the legend on the back?

I take it, the wires you see here at the lower left are those that lead to the controls?

THE WITNESS: Yes, sir.

Q All right. I show you exhibit --

THE COURT: Just a moment. Give Mr. Mc Morrow a chance to look at the back.

MR. MC MORROW: I don't understand the parenthetical reference after Great Slave Lake --

MR. EINSTEIN: They are from the Great Slave Lake. That's all it refers to.

THE WITNESS: Versus Lake Winnepeg. That is the type of fish that is hung there.

MR. MC MORROW: Well, I object to the writing on the back. If the picture is intended to prove the fact that the fish came from the Great Slave Lake, I would --

THE COURT: You do?

MR. MC MORROW: I would object because there hasn't been any testimony that this particular batch came from the Great Slave Lake.

THE COURT: Who knows.

MR. EINSTEIN: I don't think it's important.

THE COURT: I don't think it matters because, I take it, they came out of a box labeled, Great Slave Lake. But I suppose in this era of perfect confidence in one another's representations we assume that it's at least possible that they or some of them might have come from Great Slave Lake. You will vote on it later.

Q Dr. Bierman, I show you what has been marked as Defendant's Exhibit H for Identification. Would you describe that, please.

A Yes. This is a tree of smoked fish out of one of Vita's ovens. That represents the -- their regular production.

MR. EINSTEIN: I offer that in evidence.

MR. MC MORROW: I object for the same reasons as before.

THE COURT: Received.

Q Now, I will --

THE COURT: Just a minute.

THE CLERK: Defendant's Exhibit H in Evidence.

THE COURT: Now, the legend is, whitefish, regular process, smoked prior to removal from oven.

We have no definition of what regular process meant as applied to this batch. I take it, what is meant is that it's at the point they are ready for

removal from the oven.

MR. EINSTEIN: Dr. Bierman testified yesterday --

THE COURT: All right. Is that right?

MR. EINSTEIN: That they are ready for removal from the oven, yes.

THE WITNESS: Yes.

THE COURT: All right.

MR. EINSTEIN: I believe Dr. Bierman testified yesterday as to the processing parameters in producing the regular batch at Vita.

THE COURT: Well, what were they with reference to those shown in H?

Q Dr. Bierman, do you recall the temperature?

A Yes. The temperature of the regular process I believe varied between 146 and 156 degrees Fahrenheit for 30 minutes.

THE COURT: And the salt?

THE WITNESS: I believe it was in that batch 3.01.

THE COURT: 3.01?

THE WITNESS: Yes.

(Continued on next page.)

SS/rp amrl

BY MR. EINSTEIN:

Q Dr. Bierman, I'm going to show you collectively photographs marked Exhibits I, J and K for Identification and ask you if you can tell us what these represent.

A These represent smoked fish, whitefish, that were processed in Vita's plant to 180 degrees Fahrenheit for 30 minues.

Q All three photographs --

THE COURT: I, J, J?

THE WITNESS: Yes, sir.

I direct your attention to K, which is very illustrative of what happens when the fish are heated to this high temperature with some fish, where they pull away from the nail and demonstrates the need for additional support hooks in these fish.

MR. MC MORROW: I object to the answer as not responsive to the question.

I think the picture speaks for itself.

MR. EINSTEIN: I offer these three photographs, I, J and K in evidence.

THE COURT: As I understand it, these are all 180 degree cases?

THE WITNESS: Yes, the three photographs.

THE COURT: Do you know what the salt was?

THE WITNESS: I think in that produce it was 3.66.

MR. MC MORROW: We object for the same reasons, your Honor.

THE COURT: It will be received.

THE CLERK: So marked Defendant Exhibits I, J and K in Evidence.

(So marked.)

THE WITNESS: They hang with the tail up, sir, if you look at them with the tail up.

BY MR. WEINSTEIN:

Q I next show you what has been marked Exhibit M.

MR. EINSTEIN: I realize I skipped over L momentarily, your Honor.

Q I ask you if you can identify what Exhibit M represents.

A Exhibit M represents a gravity-type oven, brick overn.

It shows the charcoal pots that are used for supplemental heating. It also shows the gas jets along the bottom edge of the oven and it also indicates a partial tree of fish prepared for drying and smoking.

Q Is that Nova Scotia's oven?

A Yes, it is.

MR. EINSTEIN: I offer it in evidence.

MR. MC MORROW: No objection.

THE COURT: Received.

THE CLERK: So marked Defendant's Exhibit M in Evidence.

(So marked.)

Q I now show you --

THE COURT: One moment, please.

(Pause.)

THE COURT: The jets, the gas jets --

THE WITNESS: One long piple.

THE COURT: What?

THE WITNESS: Two long pipes running at the bottom.

THE COURT: And the flame is directed to the plate?

THE WITNESS: Up to the plate, yes.

THE COURT: And not into the chamber?

THE WITNESS: Sort of direct on both sides. Part of it will go into the chamber and part will heat the plate to radiate heat.

THE COURT: The flame will come out on the

near side of the pipe?

THE WITNESS: Yes. There are holes along the pipe that are underneath that plate.

The jet flame will come out there, part of which will be under the plate, part will be partly away from it.

THE COURT: I take it this is before any application of heat?

THE WITNESS: Yes, sir.

THE COURT: Or smoke?

THE WITNESS: Yes.

BY MR. EINSTEIN:

Q I next show you what has been marked as Defendant's Exhibit L for Identification and ask you if you can describe what that is, sir.

(Handing.)

A This is a picture of regular smoked whitefish at the Nova Scotia plant.

It demonstrates the additional body hooks employed and also the thermocoupler wires we used in the monitoring.

Q Is that after processing?

A Yes, sir.

Q What temperature was that fish processed?

5 Bierman - redirect

A This was a regular batch. This was processed at approximately 150 degrees for 30 minutes.

MR. EINSTEIN: I offer that in evidence.

THE COURT: For how long?

THE WITNESS: 30 minutes.

THE COURT: What salt?

THE WITNESS: Salt content in that product, I believe, was 4.3.

THE COURT: At what stage of the proceeding was this taken?

THE WITNESS: This is a finished smoked fish still hanging in the oven before it was removed, after the smoking operation.

MR. MC MORROW: I have no objection, your Honor, except to the language in the back representing the source of the fish.

THE COURT: It will be received.

THE CLERK: So marked Defendant Exhibit L in Evidence.

(So marked.)

THE COURT: You referred to additional supports?

THE WITNESS: Yes, the fish is hung through the tail area on a stainless steel nail and then

you will see that there is an addition -- looks like a wire coming down, a heavey wire coming down --

THE COURT: The white wire?

THEWITNESS: Yes, the silver, stainless steel wire.

THE COURT: Yes, that's not the probe wire?

THE WITNESS: No, sir, that's not.

THE COURT: The white tag with the blue strip --

THE WITNESS: They put a label on their fish, on their larger fish prior to the processing.

It's on the fish during the whole processing operation.

BY MR. EINSTEIN:

Q I next show you what has been marked as Defendant's Exhibit N for Identification, and ask you to describe what that represents.

(Handing.)

A Yes, sir, this is a tree of -- I'm sorry, a stick of fish processed at 180 degrees for 30 minutes in one of Nova Scotia's ovens --

THE COURT: With what salt?

THE WITNESS: The salt content on this fish,

I believe, is 4.46. I'm not quite sure on this one, sir.

THE COURT: Four or six; 4.4 or 4.6?

MR. EINSTEIN: I offer this in evidence.

THE COURT: This was Nova Scotia?

THE WITNESS: Yes, all prior to being removed from the oven.

MR. MC MORROW: Your Honor, I would object to this primarily because the basis really hasn't been established that these fish were processed in compliance with the G.M.P.

BY MR. EINSTEIN:

Q Did you personally supervise the processing of these fish?

A Yes, sir, I did.

Q Did you have a pyrometer with probes in the fish during the processing?

A Yes, I did.

Q Did you observe the readings on the probes and note what they were?

A Yes, sir, I did.

Q Based upon all that, can you testify from your personal knowledge these fish were processed at ~~108~~ 180 degrees for 30 minutes?

A Yes, sir.

MR. MC MORROW: I would still object with respect to the assertion that they represent fish which have a salt content of the precise amount that Dr. Bierman stated.

THE COURT: Whichever that is, 4.4 or 4.6.

Did you make notes of the experiment which you refer --

THE WITNESS: Yes, sir.

THE COURT: Couldyou tie them right down to Exhibit M?

THE WITNESS: Yes, sir.

THE COURT: Would you want to consult on that?

MR. EINSTEIN: If Mr. McMorrow wants to.

THE COURT: I told one of our judges about out testing session here yesterday.

He said he felt that he could have qualified and would have been glad to.

MR. EINSTEIN: Shall we make a guess as to which one?

THE COURT: No, you would almost certainly be wrong.

THE WITNESS: Salt content in those fish, sir,

was 4.34.

THE COURT: Four point --

THE WITNESS: -- three four.

THE COURT: That's thirty-four hundredths?

THE WITNESS: Yes. 4.34 per cent, yes, sir, in the water phase, the loin muscle.

We charted the slowest heating fish or at least the slowest heating fish that we had probes in and the highest heating fish.

The chart is demonstrated by the black continuous line which is the slowest heating fish, the red line is the highest heating fish.

The slowest heating fish was at 180, approximately 35 minutes.

THE COURT: The highest heating fish?

THE WITNESS: The highest heating fish was at about -- it reached the temperature of about 200 -- I have a report here, about 224 degrees.

It was above 200 degrees for 95 minutes.

THE COURT: How many?

THE WITNESS: 95 minutes. Ninety-five.

BY MR. EINSTEIN:

Q Would you explain to his Honor the differences in temperature?

A Sir?

Q The reason for the difference in temperature between the slowest heating fish and the hottest fish.

A There are differences in temperature within the over, also differences because of the location of the probes.

You can't be always be assured that you're in the geometric -- thickest portion and slowest heating part of the fish, and also the size of the fish will determine the heat penetration rate.

Q Before you roll that up, can you tell us during the period of time that the coolest fish maintain that temperature of 180, what is the ambient temperature in the oven and that I understand is the ambient temperature in the mid-point in the oven, is that?

A We have the two ambient temperatures.

We took the ambient in the rear of the oven and the front of the oven.

Q The rear of the oven would be the hottest -- hotter or hottest?

A It depends; on some ovens it could be the hottest and some it could not.

Q The front would be cooler in any event?

A Not necessarily.

Q Not necessarily?

A No.

When they close the doors, you could have a higher tempoerature developing in front.

Q Would you tell us what those ambient readings were?

A My chart goes up to 300 degrees and the hottest temperature exceeded 300 degrees for a period of about 85 minutes.

THE COURT: Eighty-five?

THE WITNESS: Eighty-five.

A (Continuing) The slowest heating ambient proble indicated a temperature above 300 degrees for about 20 minutes, 15 to 20 minutes.

Q Incidentally, Dr. Bierman, do you know whether in the smoking process, it is necessary for somebody to enter the oven chamber to do things during the course of smoking and cooking?

A During the end and during the smoking procedure, it is necessary to add additional charcoal to the pots to maintain the temperature.

At the termination of the heating operation, and I say the application of heat, the heat continues because of the heat in the brick walls of the oven, the

charcoal pots are removed and the smoker or his assistant has to go into these ovens and lay down a bed of excelsior and chips which are moistened and ignited and these are the manufacturer of the smoke during the smoking cycle which in the draft oven is usually at the end of the heating operation.

Q Can you tell us what the ambient temperature was on the two probes in that oven at a point in time when the smoker would be required to go in there to lay down the excelsior and ignite it to produce the smoke?

A The ambient temperatures, as I indicated, were in excess of 300 degrees when the smoker went in and when he came out he said, "If we have to smoke like this, I'm quitting."

MR. EINSTEIN: Do you want that chart marked for identification for any reason?

I don't propose to encumber the record, unless you want it.

MR. MC MORROW: I think we would like to take a look at it.

THE CLERK: Photograph marked as Defendant's Exhibit N in Evidence.

(So marked.)

MR. EINSTEIN: I next ask a group of documents

be marked as the next group of exhibits for identification.

THE CLERK: So marked Defendant's Exhibit O for Identification.

(So marked.)

BY MR. EINSTEIN:

Q Dr. Bierman, I show you what has been marked Defendant's Exhibit O for Identification and ask you if you can identify the document.

(Handing.)

A Yes, this document is commonly referred to as the whitefish petition.

Q Do you know when and with whom it was filed?

A This document was prepared and filed by the Bureau of Commercial Fisheries with the Food and Drug Administration in early to mid-1971.

Q Do you know of what the document -- what the nature of the petition is?

A Yes, sir.

Q Would you tell the Court, please?

A The petition, basically, is to amend the regulation permitting nitrate in chubs as applied to whitefish.

21 CFR 121.1230 is the food additive regulation

permitting nitrate in chubs.

THE COURT: Say that again?

THE WITNESS: 21 CFR 121.1230.

This petition is applied to whitefish, requesting and supplying data to substantiate the processing of whitefish at 150 degrees with three per cent salt, using nitrate at a hundred to 200 parts per million.

MR. EINSTEIN: I offer the petition in evidence.

MR. MC MORROW: Your Honor, I strenuously object.

I object on the basis primarily of relevancy.

I think this Court has already stated it is not going to hear evidence on an application made to the Food and Drug Administration with respect to an amendment of the GMP's.

We don't believe this is the proper forum. We don't believe this document has any bearing on this proceeding whatsoever.

THE COURT: I don't know quite what the purpose of the offer is.

MR. EINSTEIN: To place in evidence the documentation of one of our counter-claims in

this action in which we complaint of FDA's failure to act on the petition since 1971, which is causing us the problem of being here today.

MR. MC MORROW: I still fail to see the relevance, your Honor, to the proceeding which is before this Court to the questions which are before this Court, which is whether or not the defendants have violated the GMP's.

What the agency has done or not done with respect to the so-called whitefish petition is totally irrelevant to the matters before this Court.

THE COURT: I'm inclined to agree with you but at the same time I think it has a place in the case in view of what has been said about the counterclaim if only for the purpose of making the poitn clear and reviewable.

As I understand it, what we next need is that there was never any formal order of any kind entered on or anything in the nature of a determination entered on it and there was no appeal to any reviewing Court for or with respect to the action or inaction on the petition.

MR. MC MORROW: We have a threshhold objection

also, your Honor; that is that we submit this Court doesn't have jurisdiction to hear that counter-claim.

If the plaintiffs -- if the defendant --

THE COURT: I'm quite inclined to agree with you, but, again, I think, in order to have the point in reviewable shape, we need to have the material here.

This does not constitute a ruling on my part that this petition can, in effect, be re-addressed t this Court for corrective action or for the purpose of having this Court, as I presently see it, issue any order against the Secretary, but how I can say that without giving the Appellate Court, in effect, a look at what I said, "No," to, escapes me.

In other words, the fact that one is going to dismiss the compalint for want of jurisdiction is not a ground for expunging it from the file of the Court before appeal.

Better leave it in the record so that the Appellate Courts can determine whether or not you should have dismissed it.

MR. MC MORROW: Then I would want to make

sure the record reflects our objection to this line of testimony and the admission of this exhibit, primarly on the grounds this Court lacks jurisdiction to hear the counterclaim, and also in addition, that it is irrelevant --

THE COURT: In other words, you now want, I would think, you would want this received in evidence in support of your demurrer to the counterclaim.

MR. MC MORROW: For that limited purpose only.

THE CLERK: So marked Defendant's Exhibit O in Evidence.

(So marked.)

THE COURT: I wonder if we can do something to keep it in a piece.

MR. EINSTEIN: We would like your Honor to make a Xerox. It's our only copy. Maybe Mr. Morrow can even handle that.

MR. MC MORROW: Your Honor, we have a problem in that all we have is what Mr. Bierman purports to be the whitefish petition.

We don't know if that is an accurate duplicate reproduction of the whitefish petition.

It is just what Mr. Bierman purports it to be.

MR. EINSTEIN: I will stipulate with Mr. McMorrow, if he finds anything included which should not be or that has been excluded that should be included, he may supplement or change the exhibit as is appropriate, either during this trial or during your Honor's consideration of the matter.

I don't want the record to be inaccurate.

MR. MC MORROW: That was my concern, your Honor.

THE COURT: Perhaps we ought to be clear about what's what.

There appears to be at the top communications of January 28, 1972, August 6, 1971, and July 16, 1971, and then something called a supplement to Attachment 1.

I think you better police this up to see what's what.

MR. MOREY: Your Honor, might I explain?

The petition was originally submitted, I believe, April of 1971. However, it did not contain all the data at the time of submission.

THE COURT: All I want to have, to make sure that we're talking about what was before the department.

You generally straighten that out and make sure that you got it all squared away.

MR. MOREY: This was that, just supplemental data.

THE COURT: I will accept what you generally agree upon.

MR. EINSTEIN: Do you want us to consult with Mr. McMorrow?

THE COURT: Certainly.

MR. EINSTEIN: Do you have a copy available, Mr. McMorrow?

The Government advises me they don't have a copy here.

MR. MC MORROW: I'm not familiar. We don't have a copy with us, your Honor, no.

MR. EINSTEIN: I would be perfectly satisfied --

THE COURT: There is time to do it. It's not going to take a hundred years. It shouldn't take more than a day.

MR. EINSTEIN: I assume Mr. McMorrow will

product it to the Court.

THE COURT: As long as it is a real thing.

BY MR. EINSTEIN:

Q Dr. Bierman, do you know whether there has been any official action or determination of the whiteful petition by the Food and Drug Administration?

A I have not seen any and I do believe there has never been any action taken officially on that whitefish petition.

MR. EINSTEIN: You may inquire.

JD fls.

(Continued on next page.)

RE-CROSS EXAMINATION

BY MR. McMORROW:

Q Dr. Bierman, did you file the whitefish petition?

A No, sir. I did not.

Q So its understod, I believe, no communication was received by you regarding whether or not it was denied or granted?

A I have attended a number of meetings with the Food and Drug Administration in reference to the smoke fish problem, since the whitefish petition was submitted. It has been discussed and our latest meeting with the Food and Drug Administration in May of 1975, they had taken no action on that petition and I have not heard since that date that they have taken action.

MR. EINSTEIN: Does the government contend the Administration has taken action on the petition?

MR. McMORROW: Your Honour, if you will bear with me for a moment.

THE COURT: They may calmly and deliberatively have taken non-action.

MR. McMORROW: Permit me to confer one moment with the representatives of the F.D.A.

THE COURT: Yes.

(Pause)

Q Mr. Bierman, do you know who filed the whitefish petition?

A Yes.

Q What organization is that?

A The bureau of Commercial Fisheries of the Department of Interior.

Q Do you know whether or not that agency has decided to take any action with respect to the whitefish petition?

A I don't understand your question.

Q Do you know when the Bureau of Commercial Fisheries, now the National Marine Fisheries Service, the organization which filed the whitefish petition has,consequent to the time it filed the petition,taken any action to force or otherwise seek - - excuse me - - to enforce the F.D.A. to act on the petition?

A I don't know.

Q Do you know whether or not they have considered taking any action to force the F.D.A. to act on the petition?

A I don't know, no.

MR. Mc MORROW: Might I please see the photographs, the exhibits?

THE COURT: Yes.

A Dr. Bierman, with respect to the fish that were smoked at Vita Foods, can you tell me what kind of oven they

were smoked in, cooked and smoked in?

A They were smoked in an Alkar Rasmusse in electronically controlled oven.

Q These ovens have temperature and humidity controls; do they not?

A Yes.

Q Would you explain briefly again what a temperature control is?

A A temperature control, they have a recording instrument that indicates the dry bulb and the wet bulb temperature. They have an instrument panel which they can control the temperature going into the oven and the moisture going into the oven and these dial controls are set to attain certain processing parameters.

Q You've testified with respect to the gravity oven which were used by Nova Scotia, that there was a substantial variation in the temperature between one fish and another fish within the oven?

A That's correct.

Q I presume that's because the temperature varies dramatically within the oven?

A It varies because of the size of the fish, the location of the probe and the temperature in the oven, yes.

THE COURT: There, we are talking about substan-

tial differences in the temperature at the probe point in depth in the fish?

THE WITNESS: That's correct, it sensors at one point at the end of the probe and it's that point at which we are measuring the temperature.

THE COURT: So that it's really deep in the tissue.

THE WITNESS: It's hopefully deep in the tissue when you insert these, you assume based on the possessioning and the depth of the probe that you are hitting the depth of the fish.

THE COURT: If it's done right, it's really right in there?

THE WITNESS: That's correct.

THE COURT: What about - - Are they substantial differences in the ambient temperature at the surface of these fish, depending upon where the fish is?

THE WITNESS: That's correct.

THE COURT: There is?

THE WITNESS: Yes.

THE COURT: Do you know what the order of difference in the ambient is?

THE WITNESS: I think on those charts indicate

the high and the low ambient - -

THE COURT: That's at the extreme of the oven; isn't that correct?

THE WITNESS: Yes.

THE COURT: Not, as luck would have it you did not do one between the two racks?

THE WITNESS: That's correct, but I think the rear and the front of the oven would indicate the variation that you might expect in the ambient condition.

THE COURT: You think it would be moreless a slope?

THE WITNESS: Yes, it would range between those values.

Q Would forced air circulation be helpful in making the temperature uniform within the oven?

A You have to understand how these ovens operate. They control the temperature by a number of factors. They control it by the gas jet. They control it by the smoke pots, the intensity and the number and also control it by the opening in the front of the oven and in the flue opening.

THE COURT: When you say"opening in the front of the oven", is it like the old fashioned furnace of my youth that have vents on it, that you open and close or do you just put the door ajar or what?

THE WITNESS: No, this oven has it - - it's hinged on the outside frame of the oven. There are two dutch doors that are opening in front of theoven. Each door is divided into two separate doors so they can separately close the lower portion and these dutch doors are divided probably two-thirds up and then there's another set of doors a third of it way up, wo we have basically four doors that are used to open and adjust for the opening. This participate in the temperature control.

Q These are all features of the gravity oven; are they not?

A That's correct.

Q In the alcar ovens or more sophisticated electronic oven there's no need for charcoal pots; is there?

A No, sir, there isn't.

Q The doors are sealed; are they not?

A They are closed, yes.

Q And the air circulates within the oven?

A The electronic oven?

Q Yes, forced air circulates within?

A That's correct.

Q Does that have the effect of achieving a more uniform temperature?

A Yes, it does.

Q Now, you testified with respect to the batches cooking in the gravity oven at Nova Scotia Foods a substantial variation,, the highest heated fish reach a temperature of over two hundred degrees for ninety-five minutes, whereas the slowest heating one upon which you based your test is one hundred and eighty degrees for thirty minutes.

A I should point out we probed four fish and we had two ambient probes so there are records there, although I have not indicated them by a continuous line of two other probes in that oven.

Q I see.

The photograph, Mr. Bierman, appears to indicate that of those four probed fish, one of them was at one hundred eighty degrees for thirty minutes and the other three fish were at over two hundred degrees for almost ninety minutes; is that correct?

A That is absolutely correct, sir. The G.M.P. says the slowest heating fish in the oven must obtain parameter at the time of one hundred eighty degrees Fahrenheit doe thirty minutes, the slowest heating portion of the fish. That's exactly what we did.

Q You cooked in an oven - -

THE COURT: In other words, you interpret it, --

and I guess we're all agreed agreed that the regulation requires that it be not at the belly, but in the back or wherever, and that it be the lowest fish in the lot.

THE WITNESS: Perhaps I can help you out.

THE COURT: What was just crossing my mind was, There are going to be, what, several hundred pounds of fish in there at a time?

THE WITNESS: They smoke usually five to six hundred pounds in an oven.

THE COURT: That means what?

THE WITNESS: (No response)

THE COURT: What does that mean, a hundred fish?

THE WITNESS: Two hundred fish. It could be two hundred to three hundred fish.

THE COURT: Would it be appropriate - - I suppose you couldn't know without the probes in every fish; could you, to avoid over heating by simply discarding those fish which were not heated to a hundred eighty for thirty minutes?

A (No response)

THE COURT: I mean could the regulation be interpreted as meaning that those that you hold for shipment in interstate commerce must have been fish that have been cooked at one hundred and eighty degrees for

thirty minutes.

THE WITNESS: The regulation says that the slowest heating fish must obtain this parameter, that in a sense every other fish must at least attain that and because of the variation they can attain a considerable hire level.

THE COURT: What you are saying is, if you know, as you must know, that there is a cold spot in every brick oven that you cannot simply reject those or use that as a means of compliance.

THE WITNESS: Well, the processors do. If they know there's a cool spot in the oven, they will indicate that as the probing area to represent the slowest heating fish.

THE COURT: They would have their heads examined and be better off leaving that set of book vacant. Well, anyway (sic)

Q The point is, Mr. Bierman, the substantial variation in temperature within the brick oven, the gravity oven, causes these wildly divergent reading of the monitored fish in the brick oven; is that correct.

A I think you'll find as these brick ovens heat up, that's a lot of radiant heat created by the heat absorbed by the bricks so as you continue to heat in these ovens the

heat stablizes and is not as great toward the end of the cooking area as in the initial portions.

THE COURT: Let's us not go into black bodies and all that.

Q There are these variations - -

A Yes - -

Q - - within the gravity oven.

THE COURT: Might I ask one question? I take it, for processing purpose the cooking period is longer than thirty minutes.

THE WITNESS: Yes.

THE COURT: What is it if there is a standard, what is the standard of cooking period?

THE WITNESS: There is no standard cooking period. The Food and Drug Administration only wants the fish to attain - -

THE COURT: I understand that, but I take it that the processor of the fish has his own formula how long he wants them exposed to heat in the oven.

THE WITNESS: That's correct and then it's based upon the quality characteristic and the need to dry the fish initially and slowly heat it.

THE COURT: I take it here that the sixtysix minutes extra could not have been controlled.

THE WITNESS: That means that particular fish got up to temperature quicker than the other fish did so it stayed at an elevated temperature through the remainder of the cook.

Q Mr. Bierman, isn't it possible in fact - - isn't it the case that the heat is more easily controlled and it's more uniform within the electronic oven?

A That's correct.

Q So that were these fish processed in an electronic oven, there might not be the substantial variation in temperature?

A That's correct.

Q Yet you presented us with three photographs of fish which were cooked in a gravity oven.

A (No response)

Q I ask you, were these fish cooked with the expectation that samples of the fishes would be brought into this courtroom?

A Yes, these were processed in strict accordance with the G.M.P. procedure so they could be demonstrated what the fish looked like when they were processed that way.

Q The test was undertaken - - the fish were cooked on the racks, hung onto the smoke sticks, they were dried, cooked, they were smoked, they were brought out of the oven

all as part of an experiment or part of a process in anticipation of these pictures being taken and being brought into this courtroom; is that correct?

A That's correct.

Q With respect to the four pictures you took at Vita Foods, were these whitefish cooked in an Alcar oven?

A All the fish we processed at Vita Foods were cooked in an Alcar oven.

Q Did you make a similar record of your reading at Vita Foods?

A Yes, we did.

Q Did you bring that with you?

A Yes, I did.

Q Can we see it?

A Yes. Vita Foods, I must point out, that we had rented a recording potentio meter for monitoring the temperature at both Vita Foods and Nova Scotia Foods. When we got to Vita Foods, we had difficulty operating the potentio meter recording thermometer. We had to get in somebody to repair this before we could record. Consequently, the processing at Vita Foods - the charts are different than the one you will see submitted there. We used a recording potentio meter, a recording thermometer that is installed at the Vita plant. It's a leeds and north rope, twentyfour point continuous

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recording thermometer, which has four probes in each of six oven and we use these probes to monitor the fish at the Vita Food plant. Consequently, you will see a different record because the time charts speeds are different and I think the calibration of the instrument is different as far as the full scope of temperature.

At the Vita plant, there are the probes represented here in the fish and there is a seperate chart which indicates the ambient wet bulb and dry bulb temperature.

(Continued on next page)

JB:BD 3aml

THE COURT: Well --

THE WITNESS: This is a temperature chart of whitefish with four fish probes representing the left rear of the oven, the right rear, the left front and the right front of the oven.

THE COURT: This is a good moment for a short recess.

MR. MC MORROW: Thank you, your Honor. It is most appreciated.

(Recess taken.)

THE COURT: All right.

Q Mr. Bierman, in reviewing those charts which you produced, I noticed there was a good deal of consistency between the four-probe fish in the electronic oven.

THE COURT: That there was --

MR. MC MORROW: Consistency, your Honor, between the readings.

THE COURT: There was little consistency?

MR. MC MORROW: There was much -- substantial consistency.

THE COURT: All right. In the electronic oven.

MR. MC MORROW: To my layman's observation.

Q Will you confirm that?

A No, I don't think -- I think in the early

portions there seems to be good agreement. But I think you will see when the fish were up at -- in the 180 degree range where they were meeting the GMP parameters, there were some fish that got up as high as 197 degrees. So there was a differential of about 179 to 197. So there is a 20 degree spread.

Q That was --

THE COURT: That is 179 to -- to --

THE WITNESS: The slowest heating fish that we were monitoring ranged between 180 and dropped down to about 179 at one point during the 30 minute interval. Another fish in that oven that we were probing was hovering around the 197 range.

Q What about the other two fish? Could you point out where they were during that period?

A Yes. One of those fish was about 183 at its low point. And I believe the other fish was up in the 197 range.

In fact, I believe -- yes, about 198.

Q But in the raising of the temperature through the cooking process --

A Yes. Contrary to the gravity oven during the early phase of the heating of this -- in this oven, you get a fairly uniform result. And as the temperature

increases, the divergence of -- among fish becomes more pronounced. Contrary to the other oven, there is a lot of residual heat in the bricks, and the temperature in the oven is fairly substantial.

Q How long did this entire monitoring take?

A This process took five hours.

Q And at what point in that five hour period of time did the divergence between the temperature of the monitored fish begin to develop?

A I would say at about 160 degrees temperature they started to spread apart after about four hours, three and three-quarter hours of the process.

Q Now, have you personally experimented with cooking fish at other temperatures?

A Yes.

Q And for other periods of time?

A Yes sir.

Q So you have experimented with cooking fish for three hours? In other words, raising the temperature quicker?

A We haven't done too much work on increasing the temperature more rapidly, although in the gravity oven the heating cycle is quicker than it is in the controlled oven.

Q But with respect to the controlled oven, you say you haven't experimented that much with raising the temperature faster?

A No, we have not.

Q Now, to my layman's eye -- well, I will withdraw that question.

Would you explain what was actually the relative humidity as indicated on your wet bulb-dry bulb chart?

A I looked at this chart prior to this, and ours don't handle the degree of relative humidity at the lower levels. We found that generally they were below. About 20 percent. And then at the 140 degree range, we were controlling the oven so that the differential between the wet bulb and the dry bulb temperature was giving us the 40 percent relative humidity. However, at the higher temperature, at the very high temperatures of 230 -- and then we dropped down to about 220, we were unable to attain the elevated humidity of 40 percent.

Q So at the time that the fish were cooking at 180 degrees you were not maintaining 40 percent humidity in the electronic oven; is that correct?

A There was a portion of the time -- yes, I would say that during the last three-quarters of the cycle

we had difficulty attaining that higher relative humidity.

Q So these pictures that you have presented are pictures which you observed being taken of the fish cooked at 180 degrees for 30 minutes at Vita were not cooked at 40 percent humidity when they reached 180 degrees?

A I would have to check the chart. I know we had difficulty. We had the humidity at its highest point of control in the Vita oven and we were having trouble attaining the 40 percent relative humidity.

I would have to refer to a humidity chart. I noticed you had one there. If I could take a look at the humidity chart --

Q I think that's what this is.

A That's correct.

This dry bulb only goes to 212. It doesn't go to 230.

Q I don't know how to use it. So I profess my ignorance.

A Well, you can't determine the relative humidity from this chart.

Q But the point is, your relative humidity --

A We knew that we were now maintaining the differential that we had calculated beforehand that was necessary to give us the 40 percent.

Q So it was less than 40 percent humidity?

A I suspect it was.

Q Have you experimented with cooking fish at other levels of humidity?

A No sir, I haven't.

Q All right. I take it, then, that you haven't experimented with cooking fish at a combination of different temperatures and different humidities?

A That would be correct.

Q Did you invite the FDA to observe or otherwise participate in the cooking and smoking process which resulted in these photographs?

A No sir, we didn't

Q Isn't it true or -- I will withdraw that.

To your knowledge, does Mr. Sklar and the people who run Vita foods permit pictures to be taken during the investigations by the FDA of their facility?

A I don't know whether they do or not.

MR. MC MORROW: I have no further questions.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Bierman, is it feasible to arrange fish in the gravity oven so that no fish are placed in the cooler areas?

A Well, you have to understand what the cooler area is. It's a gradient of temperature differential in the oven. There is one point that is cooler either because there isn't circulation for the amount of heat in that particular area. It's not one -- not one point, but it's a gradation of heating from the area. So it would be very difficult I think to arrange fish that way.

Q And what would the effect of that be on the production capacity and operation of a plant if you tried to eliminate certain areas in the oven?

A It would reduce the production capacity out of that particular oven, utilizing the same manpower and energy requirement.

Q All right. Now, is there a -- with respect to the electronic oven, is there a difference in temperature between the fish and the ambient temperature in those ovens?

A Yes.

Q How great does that temperature difference run?

A I think during the period of the actual -- at 180 degree temperature, we had a 50 degree temperature differential between the ambient and the fish themselves.

Q In the electronic oven, is it necessary, as it is with the gravity oven, for anyone to enter the oven during the cooking and smoking procedure?

A No sir.

THE COURT: Just a minute. Could I hear that question?

MR. EINSTEIN: I said --

THE COURT: In the answer.

(Record read.)

Q Now, you testified on cross-examination that you had trouble maintaining a 40 percent relative humidity in the electronic oven at Vita. Could you explain what happened?

A We set the dry bulb control to obtain the temperature and tried to maintain the temperature as close as to 180 degrees Fahrenheit as we could during the 30-minute interval. You just don't get to 130 and stay there. It has to be programmed and adjusted. so you don't overswing by a lot or underswing that temperature.

Q You said 130. Did you mean 180?

A Yes, I did. I am sorry.

Q All right, continue.

A The wet bulb is programmed and we set it to get the differential that was required to maintain the 40 degrees. When we set it to attain that differential, we were unable to attain the differential and we adjusted the wet bulb control accordingly and we were still unable to

attain it.

Q You mean the equipment didn't permit you to obtain that 40 percent humidity at that point in the processing?

A That's correct.

MR. EINSTEIN: No further questions.

RECROSS EXAMINATION

BY MR. MC MORROW:

Q Now, you stated that the equipment didn't permit you to maintain the 40 percent relative humidity. Do you know how long Vita has had this equipment?

A Not for sure. But I believe they had it in there for four or five years in that installation.

Q Did they tell you -- did the smoker or the operators of the ovens tell you it was not possible to achieve that humidity?

A No, they did not.

(continued next page)

Q Did they tell you what experiments they had done to achieve that humidity?

A No.

Q Did they tell you what constituted the equipment to see if that humidity or a higher humidity could be reached?

A No.

Q Did they tell you whether or not they consulted with any experts, whether it be engineers or experts on heat transfers within foods to see if that humidity could be reached?

A No, they did not.

MR. MC MORROW: No further questions.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q You do know how to run one of these electronic ovens?

A I know how to control them with assistance from a smoker.

MR. EINSTEIN: All right, thank you. I have no further questions.

MR. MC MORROW: No further questions.

THE COURT: You may step down.

(Witness excused.)

MR. EINSTEIN: May we recall Dr. Melvin Eklund?

D R . M E L V I N E K L U N D , having been previously duly sworn, testified further as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Now, Dr. Eklund, would you describe for us exactly what is a Clostridium botulinum?

MR. MC MORROW: May it please the Court --

THE COURT: Yes sir.

MR. MC MORROW: Your Honor, at the conclusion of Dr. Eklund's -- or, excuse me, when he had stepped down from the witness stand on Monday, I believe that you had stated that the testimony that he was about to give us was almost certainly irrelevant, and unless the defendant -- that you said at that point that it becomes irrelevant -- and you stated then that -- you stated to defense counsel, "If you want to submit an offer of proof so it will be clear what we are passing up, then I think you don't have to do it right this instant. But perhaps you, before you let Dr. Eklund escape to the West Coast, you can sit down with him and prepare and go over the proof that he would have made, so that we can make that part of the record."

Am I to understand that this is an offer of proof?

MR. EINSTEIN: s am offering it as testimony. If your Honor holds that it is irrelevant, it will become an offer of proof.

THE COURT: Yes. I do not depart from the ruling I made earlier.

MR. EINSTEIN: Now, your Honor, I would like to be heard for just a moment on the relevancy, at least this particular group of questions that I am now addressing to Dr. Eklund.

The regulation as proposed and adopted by -- shown by Plaintiff Exhibits 1 and 2 in evidence, it is based upon the authority, 22 USC 342(a)(4), which is the insanitary condition provision of the adulteration statute. I think that if your Honor is going to make a determination as to whether -- and I might add that the regulation is directed entirely as is shown in its preamble toward the problem of bolutinum or Clostridium botulinum in the fish. I think if your Honor is going to make a determination as to whether the regulation is authorized under the statute, you have to know a little bit about what this organism is, where it

exists, how it finds its way into the fish. And that is the purpose that we are offering this evidence at this time.

MR. MC MORROW: Your Honor, that is part of the administrative record. That is what the rule-making procedure is all about.

THE COURT: I think here -- if I grasp what he is after -- he's after his other point on insanitary.

MR. MC MORROW: But, your Honor, we have -- we have been through this once before on Monday. We are alleging a violation of the regulation which is a particular --

THE COURT: That's right. But what he is saying is, if the regulation is on its face totally unauthorized, that can be reached here. And if -- therefore, we have to know what hinge word insanitary means and where it does extend to the present case.

That's as I understand his offer, this part of the proof.

MR. MC MORROW: Well, may I have an explanation as to --

THE COURT: You see, the emphasis before on

his -- on the no claim of filth contamination of that kind from external intrusions during the processing procedure.

MR. MC MORROW: Will you bear with me one moment, your Honor?

THE COURT: Yes, certainly.

MR. MC MORROW: Your Honor, the regulations themselves purport to establish regulations for the processing or manufacturing of foods under sanitary conditions. Now, we submit that the question of whether or not the regulations or the -- that it is an issue which should be addressed to the administrative record and whether or not the administrative record supports the determination.

THE COURT: For one thing it can't be addressed to them effectively because they have no power of effectively passing on them. And that is, whether or not their regulation is authorized by the statute. Their belief that it was would be -- it would be entitled to consideration by a court since they are the administrative body charged with enforcement of the act. They would be entitled to that deference and that respect. It could not be decisive of it because that is peculiarly the question for

judicial determination.

Now, the argument here is that it is not laid to rest by the failure to appeal directly from the regulation by proceedings in the appropriate reviewing court, but can be brought up collaterally if it goes to the total want of authority to adopt such a regulation.

MR. MC MORROW: But isn't that a legal determination that must be made by the Court with reference to what is in the administrative record? That is our position.

THE COURT: No.

Q Would you tell us, then, Dr. Eklund, what is Clostridium botulinum?

A A Clostridium botulinum is a species --

THE COURT: Now wait a minute. Could you spell the word?

THE WITNESS: Yes. I already have it written out for the reporter.

THE COURT: And me, too.

THE WITNESS: I am sorry. C-l-o-s-t-r-i-d-i-u-m. The next word is botulinum, b-o-t-u-l-i-n-u-m.

Clostridium botulinum is a species of bacteria that produces a spore. And it grows well

under the absence of oxygen. This species --

THE COURT: Wait a minute. Produces a spore.

THE WITNESS: Produces a spore. And grows in the absence of oxygen.

THE COURT: The spore --

THE WITNESS: The spore, when it germinates, it will grow into a vegetative cell. And in that state it grows in the absence of air.

THE COURT: A spore when it what?

THE WITNESS: It germinates much like a seed. It germinates into a vegetative state in which it multiplies. It is in this vegetative state that it grows and produces the lethal toxin in this --

THE COURT: Wait a minute.

Yes?

THE WITNESS: In this species there are types that are designated as Type A through Type G.

THE COURT: D?

THE WITNESS: A, B, C, E. F. G. They are designated by these letters because they each produce a different toxin that is neutralized by a specific antitoxin.

THE COURT: Just a minute.

Yes?

Q Can you describe for us exactly what is a spore?

A A spore is a state of the organism in which it is most resistant to heat and other physical and chemical treatments.

Q Now, generally --

THE COURT: Wait a minute.

Yes?

Q All right. Where is the bacteria found?

A The Clostridium botulinum organism is found very frequently very frequently in marine areas, soil samples and other samples ejected from nature.

THE COURT: Wait a minute. Marine soil samples and --

THE WITNESS: And many other natural samples that are from nature. In other words, samples that have been in contact with soil or perhaps mud from the marine or fresh water areas.

Q How does the bacteria find its way onto a whitefish?

THE COURT: Onto?

Q Onto or in a whitefish?

A The spore find its way into a whitefish merely by accident. That is, the organism -- or the

whitefish, as it is swimming in its environment, may pick this up from the marine sediments through ingestion of food products -- foods and also from perhaps stirring up the mud samples to which it may adhere to its exterior.

Q Now, respect to a live fish swimming around in a lake, if you were to take that fish out of the water and examine it, if it had any spores, where would they be found on the fish?

A The spores would be confined mainly to the intestinal tract or the exterior of the fish. I believe it is generally regarded that animal flesh in general is sterile.

THE COURT: Is sporeless?

THE WITNESS: No. I believe that in general that the fish or animal flesh is considered to be free of micro-organisms. I am speaking mainly of bacteria when I say micro-organisms.

Q Do you know the source of the whitefish currently utilized by the industry that produces hot smoked whitefish?

A Yes.

THE COURT: Just a minute. Could you repeat the question?

Q Do you know the source of the whitefish

currently used by the industry in processing their hot smoked whitefish?

THE COURT: Could you read that?

(Record read.)

MR. MC MORROW: I would like to object to this line of testimony. This is all in the administrative record and I don't see how it goes to the question of sanitary questions.

THE COURT: I heard that. I quite understand.

Q You may answer.

A Will you repeat the question?

Q Where do the fish that are currently being processed come from?

A In talking with the different processors of whitefish, they tell me that the greatest percentage of the whitefish comes from the Great Slave Lake or Lake Winnipeg in Canada.

MR. MC MORROW: Objection, your Honor. That is hearsay.

THECOURT: Yes.

MR. EINSTEIN: We have also had testimony on that directly from Mr. Sklar. I think that corroborates it.

Q Now, have you recently conducted some tests

to determine the incident of spores with respect to fish obtained from these two lakes?

A Yes. We have received live fish from these lakes.

MR. MC MORROW: Your Honor, I would like to state again my objection for an additional reason, that this relates to work that Dr. Eklund has done subsequent to the promulgation of the GMP.

THE COURT: Yes, I understand.

MR. MC MORROW: And not only shouldn't it be presented tothis Court first, but it should be presented to the agency.

THE COURT: Yes. I quite understand.

Q Will you tell us the results of those tests?

A Yes. We examined 49 whitefish both from Lake Winnipeg and from the Great Slave Lake of Canada. And from these we found that 4 out of the -- 4 of the 49 did contain this -- the spores of Clostridium botulinum Type E.

Q Now, I believe you testified there were 18 from Lake Winnipeg; is that correct?

A Yes. We did examine 18 samples for Lake Winnipeg. This is the entire fish that we examined.

(continued next page)

Q Four of those had spores?

A Four of those did have spores, that's correct.

Q Out of 31 from Great Slave Lake none had spores; is that correct?

A That's correct.

Q Now, have you also recently examined from some fish obtained from various processors throughout the United States including Nova Scotia?

A Yes. I have been very interested in the level of the number of spores in a product. And as kind of a guideline in helping us develop alternative -- alternate processing parameters, we have examined 79 processes. This is the cooked or smoked whitefish from five different processors in New York. Of the 79 we did not detect any spores in the samples.

I must clarify this, however, that if additional samples were examined one may occasionally find a spore present. The thing I want to emphasize on this is that the level of spores in the samples was undoubtedly very low.

Q Those 79 fish that you examined, how many of them were from Nova Scotia, the defendant in this case?

A 24. Excuse me, 27 samples were from Nova Scotia.

Q None of those had spores?

A None of those had spores.

Q Now, generally speaking, do you know how many spores you would expect to find in any particular whitefish if it were to bear spores at all?

A I do not have direct information on this. We attempting ourselves to get a number of spores in the fish from Lake Winnipeg. That would be on the basis of a program of fish. But to date we have not found any on the samples that we have set up for this type of analysis. The work that has been done -- and I am quoting from the literature on this -- some work that was done by Paul Pace of the Milwaukee Health Department has shown that out of 101 fish -- 101 chubb samples, that four of these contained botulinum Type E organisms. Of these, three of these fish contained one spore per fish. And these fish weighed approximately 115 to 150 grams. In one of the fish two spores were found.

Q Could you translate grams into ounces for those of us who are not as yet weaned from the traditional system?

A Approximately 454 grams per pound.

Q Now, based upon the work that you have done and the literature that is available, do you have an expert opinion as to the maximum number of spores that would

exist naturally in a whitefish, or, say, one from four to five pounds?

A Based upon this, I would say I believe the whitefish that are used range somewhere in the neighborhood of three to four pounds. So if one were to base this on a -- it would be -- each chubb would be approximately -- three chubbs would make the equivalent weight of about one pound. So I would say it would be somewhere in the neighborhood of, based on a four-pound fish, somewhere between 12 and 16 spores per fish.

Q Would you expect to find a million spores in a fish?

A It would be very highly improbable that you would find this level of spores. This is correct.

Q Would you expect to find 100,000 spores?

A Again, this would be highly improbable.

Q Or even 10,000 spores?

A 10,000 spores, I would say also. The total bacterial count -- this is the bacterial number of bacteria, many times do not -- on a fish do not even exceed 10,000. And the spores or the anaerobic bacteria would not constitute probably a tenth of this percentage of this population.

Q So what you are saying is you wouldn't find

10,000 bacteria on a -- spores on a fish of all kinds of bacteria?

A Right.

Q And, of course, botulinum is one very small component of the bacterial spores?

A There are other bacteria, yes.

Q If you even dropped it to 1,000 spores on a fish of three or four pounds, would you expect to find that many botulinum spores?

A One may occasionally find these levels in the intestinal tract of the fish. But on the -- or on the surface. But I don't think you would ever find this level in a fish -- fish flesh.

Q Are there various factors, Dr. Eklund, which affect the wealth of spores and the production fo spores?

A Yes, this is true. This is what actually constitutes health safety in many food products. It is not only one processing parameter or one condition that governs. It's the combination of a number of these different processing parameters.

Q Is there a relationship between the number of spores present and the possibility that those spores will outgrow and produce the fatal or possibly fatal toxin?

A This is correct.

Q So that if you had a million spores, it is more likely that they would grow and produce a toxin than if you had a hundred spores?

A Yes. It is agreed generally among the microbiologists that the number of spores you use in any test has a great bearing on the chemicals or heat treatment that is used. In other words, the more -- the greater the number of spores, the greater amount of the chemical that would be required to inhibit its growth.

Q Now, are you familiar with the heat and salt requirements of GMP's or 21 CFR 128A?

MR. MC MORROW: Your Honor, I object to this line of testimony. We are getting into the heart now of scientific data which supports the GMP's.

THE COURT: Yes.

MR. EINSTEIN: I agree.

THE COURT: The question --

MR. EINSTEIN: I asked him if he is familiar with either the heat or salt requirements of the GMP.

THE WITNESS: Yes, I am.

THE COURT: Well, I assume he is. But the next question is the one that counts. Anyway, he's bound by it.

MR. MC MORROW: I will wait for the next

question.

MR. EINSTEIN: You may as well stay on your feet.

Q Are you familiar with the research that led to the development of the GMP?

A Yes, I am.

MR. MC MORROW: Objection, your Honor.

THE COURT: Are you familiar with what?

MR. EINSTEIN: The research which led to the development of the GMP.

MR. MC MORROW: I withdraw my objection. Then I will wait for the next question.

Q Are the GMP's designed to inhibit the outgowth of spores under various circumstances?

A The work that was done to develop, or the data that was developed for the GMP included one million spores.

MR. MC MORROW: Your Honor, the answer is not responsive to the question.

MR. EINSTEIN: Well --

MR. MC MORROW: It's either yes or no.

MR. EINSTEIN: I would agree with Mr. Mc Morrow.

Q Are the GMP's designed to inhibit the outgrowth of spores under various circumstances?

A Yes, they are.

Q Do you know what spore level per fish was used in determining the processing parameters of the GMP.

MR. MC MORROW: Objection, your Honor. Now we are going to the heart of the administrative record. These matters were all considered by the agency. What this is divulging into is a trial de novo on the scientific evidence which was before the agency. And I think it's totally improper. And I believe that this is what your Honor ruled on Monday, that is was irrelevant.

THE COURT: Let me hear the question again, please.

(Record read.)

THE COURT: Objection sustained.

If you want to ask him whether he made some submissions to the department in connection with the adoption of the GMP, he can answer that question.

Q Well, did you make any such submission, Dr. Eklund?

A No, but our agency did.

Q All right. What submission did they make?

A The submission they made was based on one million spores.

THE COURT: On what?

THE WITNESS: One million spores.

THE COURT: No. If you did make submissions, and is that --

THE WITNESS: Your Honor, our agency did. I did not. I did not personally.

THE COURT: I mean --

Q What is the basis of the submission made by your agency?

THE COURT: When was it made?

THE WITNESS: I didn't understand your question.

Q When was the submission made to the FDA by your agency, National Marine Fisheries Service?

A I don't know the exact date. I believe somewhere in the late sixties, as I recall.

THE COURT: The late --

THE WITNESS: Late sixties. I don't know the exact date. I'm sorry.

Q What spore level was that submission based upon?

MR. MC MORROW: Your Honor, I object again.

THE COURT: I think that objection must be sustained.

He may be asked whether the submission did

deal with the type of investigation or law that he's been outlining to us here.

MR. EINSTEIN: I frankly don't understand the distinction. I was asking --

THE COURT: All right. Did the submission which was made deal with the nature of the botulinum that we have in question here, its occurrence, its what -- what do you call it, the etiology, and all the rest of it.

Q Well, can you describe, Dr. --

THE COURT: No. Did it.

Q Did it deal with those factors?

A Would you repeat that questi on again? I didn't --

THE COURT: I wouldn't dare try.

(Addressing reporter) Maybe you can.

(Record read.)

THE WITNESS: Yes. But at that time we knew --

MR. MC MORROW: The answer is not responsive.

THE COURT: Just a moment. This may be important to you, the rest of this. And you can move to strike it afterwards.

Yes, but --

THE WITNESS: Yes, but at the time much of the

the work was completed -- excuse me. At the time that much of the work -- when this was done we were actually in our beginning or infancy, as far as the -- our knowledge of what the spore levels were. We knew that the fish did contain the spores, but we had no idea of what levels to expect in nature.

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MR. MC MORROW: Your Honor --

THE COURT: That's what you want for your work.

MR. MC MORROW: Precisely.

THE COURT: Okay.

MR. MC MORROW: I move to strike the response as not being responsive, but --

THE COURT: No. I think it's what I expect. In other words, it dealt with it, but his present position is that at that time they really didn't know enough to make a submission of the completeness that they would make if they were invited to make the first fresh submission today.

MR. MC MORROW: And I might point out to the Court --

THE COURT: Is that right.

THE WITNESS: Yes.

THE COURT: All right.

MR. MC MORROW: I might point out to the Court that they don't have to be invited. They were invited in 1970 when the regulations were promulgated.

THE COURT: I quite understand.

Q Now, in that submission that was made prior to the adoption of the GMP, do you know what spore levels

per fish was used in determining the processing perameters that ultimately became embodied in the GMP.

MR. MC MORROW: Your Honor, I object again.

THE COURT: No, I think -- I think what we want is, was there a spore level used as a bench-mark perameter -- call it what you will -- in the bureau submission.

THE WITNESS: Yes. This was based on --

THE COURT: All right. Yes, there was.

THE WITNESS: Yes, there was.

Q What was the spore level?

A One million spores.

THE COURT: Sustained. The objection is sustained.

MR. EINSTEIN: All right.

Q Now --

THE COURT: Now, if you were asked today to make a submission, would you use the same spore level?

THE WITNESS: I have to clarify that.

THE COURT: No, you can't. In other words, would you make the same submission if asked to make --

THE WITNESS: I would say, no. I would base

this on the radiant level of spores.

MR. MC MORROW: I would suggest that that is totally irrelevant.

THE COURT: I think all we are interested in is to make exactly the point that time has passed, learning has increased, but that there was a submission in this area on these very points at the time.

Inadequate? Imperfect? Unlettered by today's standards? Perhaps. But it dealt with the topic.

MR. MC MORROW: Bear it in mind, we are talking just about the information submitted by the agency with which he's associated.

THE COURT: Yes. Well, we don't know whether he was associated with a particular work at the time.

Q Now, Dr. Eklund, have you had occasion in the past few weeks to examine these A through L which constitute the so-called administrative record?

A Yes, I have.

Q All right. At that time that the GMP was passed, were you also familiar with the spore level upon which it was based?

A I am sorry. I didn't quite --

Q Was the BMP designed to inhibit spores at a certain quantity or level per fish?

A Yes, they were.

MR. MC MURRAY: Your Honor, I object. He's not in a position to conclude what the agency --

THE COURT: No. I think if he wants to point to a particular tab, that might help us all.

MR. EINSTEIN: Well, I think he was familiar, your Honor, and he said that he was, with what the agency was doing at the time and based on reading all of the --

THE COURT: No. You asked him, has he examined the material in Tabs A through L and can he say what spore level was --

MR. EINSTEIN: Was the target.

THE COURT: -- the assumption of the action at the time.

MR. EINSTEIN: Yes.

THE COURT: And he answered, yes.

MR. EINSTEIN: All right.

Q What is that spore level?

MR. MC MORROW: I object to that because now he's submitting his judgment for the administrative agency.

THE COURT: No, not at all. He's being asked whether he could point out to us in what is claimed to be the administrative record the spore level determination or assumption used in adopting the regulations, and he said he could.

MR. MC MORROW: But how does he know that, your Honor? That is a --

THE COURT: I don't know. Maybe that is something that scientists know. Because these are in large part or in some part scientific submissions.

Q All right. Do you know what that spore level was?

THE COURT: No. That is not the point. Can he point to what he relies on in the administrative record to support that statement that he has just made.

MR. EINSTEIN: I was going to ask him.

THE COURT: That they had a benchmark. The question of what one they used is not before us.

MR. EINSTEIN: Well, I would -- all right.

Q Can you in that record, Doctor Eklund, point to any of the tabs which indicate what the spore level relied upon by the Food and Drug Administration -- what it was.

A I am not positive I can.

MR. MC MORROW: Your Honor, I object.

THE COURT: What is that?

THE WITNESS: I am not positive I can point to a specific tab involved. No.

Q Did you gather by reading all of these tabs and all of this information a spore level that was used by the administration.

MR. MC MORROW: Now, again I object. He's being asked to substitute his judgment for that of the agency.

THE COURT: No, he is not. He is being asked to help me. At anytime I can get an expert witness on the stand, I will use him as a teacher. I don't agree to be bound by it if I find out he was wrong. I mean I once caught a Latin teacher in a mistake. And I expect if he makes a mistake I will catch him, too, with your help.

But what I want to know is, he says that he believes that he can determine from this administrative record the assumption of the regulations as to spore level, right?

THE WITNESS: That, I believe, is correct, sir. I have to clarify this one thing further. At the

time I was with the Bureau of Commercial Fisheries, which I have been with since '62, we have quarterly reports that each laboratory submits in which each other laboratory receives. I was acquainted with this work as it was progressing at the Ann Arbor Laboratory. I was also familiar with this work through contact with Dr. Ratowsky. I had several scientific meetings, and also through other communications. So I was continually in contact with Dr. Ratowsky during the course of these settings.

BY MR. EINSTEIN:

Q Can you tell us based upon all of your knowledge what the spore level was?

A The majority of this work was based on one million spores.

MR. MC MORROW: Objection, your Honor.

THE COURT: One million per what?

THE WITNESS: One million in the case of -- first of all, I have to clarify that the GMP's and the majority of the work that was done was on hot smoke chubs, and that they -- the work from -- this was extended to all other fish species.

Q One million spores per fish?

A Yes. Chubs, which varied, like I mentioned earlier, about 115 to 150 grams, or perhaps a broader range.

Q That is a quarter pound fish?

A Approximately a quarter pound.

MR. MC MORROW: I object. I don't think the answer was responsive. I don't know.

THE COURT: No. I think -- I think I will have to rely on you gentlemen to point out to me whether or not -- anything in the administrative record here, or what is claimed to be the administrative record, that would bear that out.

MR. MC MORROW: But he -- I believe he was referring to the work of Dr. Ratowsky.

THE WITNESS: Yes.

THE COURT: Well, I think --

THE WITNESS: Also -- excuse me.

THE COURT: Isn't that what is under A or under Tab B?

Q Is the work of Dr. Rakowsky employed in the --

A There is some also of Dr. Ratowsky. And also some work of --

THE COURT: Just a moment. Isn't that work Dr. Ratowsky under Tab B with relation to FDA Contract Number 63-77? Isn't that the Ratowsky work? What

is --

MR. FRIEDE: Tab G. G-5.

THE COURT: B-5.

MR. FRIEDE: G-5.

THE COURT: I'm sorry.

MR. FRIEDE: And --

THE COURT: Just a minute. I am just never going to get the -- oh, here it is.

THE WITNESS: G-5.

MR. EINSTEIN: He's in F-42.

THE COURT: F-42.

MR. EINSTEIN: Yes, your Honor. G-1.

THE COURT: These aren't quarterly reports.

MR. EINSTEIN: No. But these are all literature that was supposedly --

THE COURT: Yes. But what I want to know is this. The statement that was made here of familiarity with the quarterly reports of Dr. -- how do you pronounce his name?

THE WITNESS: Ratowsky.

THE COURT: I take it, the Bureau -- now, which are they? Are they in here at all.

THE WITNESS: May I make a comment?

THE COURT: I see B is University of Wisconsin. This ought to be -- or Michigan State? Which is it?

MR. EINSTEIN: Your Honor, tne point that I am trying to make here is really a simple one. And that is that Dr. Eklund through his review of the administrative record and through his knowledge of the research and what was being done at the time that let up to the promulgation of the GMP is able to state that GMP --

MR. MC MORROW: Your Honor, I object to this.

MR. EINSTEIN: I am making an offer of proof. How can you object to an offer of proof?

MR. MC MORROW: You have your witness here. Elicit testimony from your witness.

MR. EINSTEIN: Well, you keep objecting. I will be glad to.

MR. MC MORROW: That is because it's all been considered by the administrative agnecy.

THE COURT: You see --

MR. MC MORROW: And you have had five years.

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THE COURT: He said that he knows what spore basis was the assumption of the regulations. I am trying to find out how he could say that in light of the administrative record. He says he couldn't put his finger right now on a particular part in the record. And then the reference to the work of Dr. Rakowsky or whatever his name is --

THE WITNESS: There was additional work by a Dr. Christianson and Dr. Foster from the University of Wisconsin which is in the record.

THE COURT: But on the basis of this, he says he draws the inference, which if for you gentlemen to agree with or disagree with, or whatever, that it was based on a million spores a fish.

BY MR. EINSTEIN:

Q Now, do you have an opinion as to what it is scientifically reasonable to base the GMP regulation on a million spores per fish, given the number of spores that exist naturally and the relationship between spore lodes and outgrowth?

MR. MC MORROW: Your Honor, I must object. This is totally inappropriate here.

THE COURT: Yes. Objection is sustained.

MR. EINSTEIN: Does he -- may he answer as an

offer of proof? Or would your Honor --

THE COURT: May I hear the question.

(Record read.)

THE COURT: To have based in 1970. Okay.

(Record read.)

THE COURT: On the assumption of one million spores per hundred and fifty gram fish. That's the question, isn't it?

MR. EINSTEIN: Well, that's the first half of the question. I will ask the second half separately.

MR. MC MORROW: Your Honor --

THE COURT: All right.

MR. MC MORROW: Your Honor, you sustained our objection. He is making it an offer of proof.

THE COURT: Sustained.

MR. MC MORROW: Yes. He wants to make it as an offer of proof.

THE COURT: Yes.

MR. MC MORROW: Please bear with me. I am not entirely familiar with -- fully familiar with the notion of an offer of proof.

THE COURT: If you want to check the procedure --

do you want to take a moment on that? Perhaps you might as well.

MR. EINSTEIN: You always confuse us with these new rules.

THE COURT: I think in the first place they change the old civil rule, didn't they?

MR. EINSTEIN: Yes. It's now Rule 103.

THE COURT: I mean the old rule on offer of proof.

MR. EINSTEIN: In the Federal rules of Civil Procedure.

THE COURT: Yes.

MR. EINSTEIN: That's been abrogated.

THE COURT: Completely abrogated.

MR. EINSTEIN: That's my understanding. And replaced by 103 of the Rules of Evidence.

THE COURT: Do you have your copy handy?

MR. EINSTEIN: Do you have yours?

MR. MC MORROW: Yes.

MR. EINSTEIN: Let me make sure I am right. What was the number of the old rule?

THE COURT: Do you have it?

MR. EINSTEIN: It was formerly Rule 43C. And that has been abrogated and replaced by Rule 103 of

the Rules of Evidence.

THE COURT: When I turned to Rule 43C in the rule book, it says that if --

MR. EINSTEIN: Right. Now, if we turn to 103 --

THE COURT: The last sentence in 103B.

MR. EINSTEIN: It gives your Honor the power to direct the making of an offer in question and answer form. It comes within 103A2 and 103B.

MR. MC MORROW: Your Honor, as long as you have made your ruling, the character of the evidence is -- this is not the form in which it was offered. The objection that the Government has made, and your ruling sustaining that objection -- and then this would appear to be simply an offer of proof.

THE COURT: Oh, no question about it. It's received on that basis only. And, you see, the one thing that that rule doesn't quite say, but it would seem to me, common sense that you have a free shot at it on cross without waiving your objection or the ruling excluding it, because if the purpose is to make available to a reviewing court the reality of the material offered as proof, I think it would have to be -- it's net reality as measured after adequate cross-examination is you chose to do

so.

MR. MC MORROW: But at what point, your Honor, does this entire proceeding become a trial de novo on the regulation.

THE COURT: It hasn't become it at all. But I have proceeded on the assumption here that the one thing that we have to be clear about is, since counsel are in apparent good faith claiming a rather radically different view of the rule of the administrative law that we are dealing with, and could conceivably right, that it's important for the Court of Appeals to know whether it was all an empty charade or not.

MR. MC MORROW: My concern, your Honor, is that I cannot reproduce here the deliberative process of the administrative agency which formulated the regulation. And, indeed, I cannot substitute my judgment, nor can I ask that of the agency in deciding the --

THE COURT: Yes. But I think that the agency is entitled to a sort of conclusive presumption that it proceeded with insight and intelligence, and that it must be taken to have rendered whatever decision was feasible. Now -- not feasible. Whatever decision is reasonable in the

circumstances of time and place, and that it's action is not open to challenge except on the conventional grounds. That is, if there was no evidence to support it, if it proceeded arbitrarily, if it exceded its authority, or if the action it took was necessarily a deprivation of life, liberty or property without process of law. But certainly not to be -- not to be required here to prove that they made a judgment which would be in agreement with the judgment that the Court might have made or some other District Judge might have made. That certainly is not their problem. All they have to do is show that they were rational.

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DIRECT EXAMINATION

BY MR. EINSTEIN: (Cont'd.)

Q Dr. Eklund, let me rephrase my question to you. Do you have an opinion as to whether it is scientifically reasonable to have based the GMP regulation on one million spores that was known at the time of the adoption of GMP in 1970 as to the spore levels found in nature?

A I would have to base their -- I don't remember exactly --

THE COURT: You object to that question?

MR. MC MORROW: Absolutely, I object.

THE COURT: Objection sustained. The answer is taken as an offer of proof.

MR. EINSTEIN: Thank you.

A I don't recall the exact dates where Mr. Paye's work was done regarding a number of spores per sample. There was earlier work from England and also from the Pacific Coast -- from the East Coast of the United States -- also demonstrating low levels of spores per gram of fish.

Q Based upon -- well, can you answer my question with a yes or no as to whether it was scientifically reasonable, to the best of your knowledge, at the time of the

adoption of GMP, in late 1970, to have based it on a million spores

MR. MC MORROW: I object, your Honor.

THE COURT: Sustained, answer taken only as an offer of proof.

A As I say, I don't recall the exact dates of the publications on when the spore levels were taken but I would say on that basis of the other data that I'm familiar with in publications, yes, I believe there was an overkill.

(Continued on next page.)

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THE COURT: Was it reasonable, was the question? Was it scientifically reasonable to base the regulation on an assumption of one million spores per hundred fifty grams of fish?

THE WITNESS: I think this is very difficult, sir, because this has always been the concern of microbiologists as to actually what spore levels or what chains of bacteria any given system should have, a million spores was used.

I believe this was based a lot upon the earlier work that was done --

THE COURT: All you're asked, you see, this action taken on a day in history, October --

MR. MC MORROW: 1970 was the promulgation.

MR. EINSTEIN: November 13th.

THE COURT: November 13, 1970, was it scientifically reasonable to base the regulation on that day issued on the assumption of the possibility of a million spores per 150 gram of fish occurring?

THE WITNESS: I would have to answer no.

BY MR. EINSTEIN:

Q Based upon the information which you have as of today's date on the studies as to spore levels, do

you have an opinion as to whether the regulation is at this time scientifically reasonable?

MR. MC MORROW: Your Honor, again I object for relevancy grounds on both bases.

THE COURT: Objection sustained.

The answer will be taken as an offer of proof.

THE WITNESS: I would say the spore level, yes, is too high.

Q Would you explain to the Court why you feel that the regulation is scientifically unreasonable?

MR. MC MORROW: Again I object on relevancy grounds.

THE COURT: Objection sustained..

The answer will be taken as an offer of proof.

A Because I would say it's very infrequently that you would ever find this level of spores on a fish.

THE COURT: This level --

THE WITNESS: This concentration of spores on a fish.

Q Dr. Eklund, are you familiar with the history of botulism in smoked fish products during the past century?

A Yes.

Q Dr. Eklund, I'm going to show you -- do you know, incidentally, how many outbreaks of botulism there

have been associated with commercially processed hot smoked fish since 1899.

MR. MC MORROW: I object. The testimony is irrelevant.

MR. EINSTEIN: This also goes to the equities of the case, the necessity of any injunctive relief.

MR. MC MORROW: The issue is whether or not the GMP is violated.

This testimony is irrelevant to that issue. It's in the record in addition, your Honor.

THE COURT: What's that, sir?

MR. MC MORROW: It's in the record as well, your Honor.

THE COURT: Is it in the administrative record?

MR. MCMORROW: I don't know. If this piece of literature --

THE COURT: But the data are in the record.

MR. MC MORROW: The history of outbreaks is in the record.

MR. EINSTEIN: I don't believe that's entirely true.

THE COURT: For your present purposes and on

this line of question, the objection is sustained and the answer will be taken as an offer of proof.

A There were approximately 10 outbreaks during this period of time.

Q Are you familiar with the -- strike that.

Do you know of any outbreak of botulism from hot processed smoked fish since 1963?

A No, I do not.

MR. MC MORROW: Objection for the same reason as before.

THE COURT: Sustained.

The answer accepted as an offer of proof.

Q Are you familiar with the work by --

THE COURT: Just a minute.

(Pause.)

MR. EINSTEIN: Your Honor --

THE COURT: Just a minute.

(Pause.)

THE COURT: Yes, sir?

MR. EINSTEIN: I believe this evidence is relevant not only with respect to the underlying basis of the regulation which of course we challenge, but with respect to whether your Honor

should in fact grant any injunctive relief if you find there has been a basis, find there's been a violation, excuse me, of the regulation.

There is an area of equitable discretion even in a case like this and the evidence which we're now attempting to develop, I think, is designed --

THE COURT: I'll consider that separately because I do not think that that is necessarily the case.

MR. EINSTEIN: That is in part the purpose of this evidence.

THE COURT: I understand that. I understand it is your view that nobody has been hurt and there is little chance of anybody being hurt, so the whole thing could wait until later.

MR. EINSTEIN: That's correct, your Honor, or wait until not at all.

BY MR. EINSTEIN:

Q Dr. Eklund, I show you a publication entitled "Sixty-Five Years of Human Botulism in the United States and Canada," by Dr. --

THE COURT: What kind?

MR. EINSTEIN: "Sixty-Five years of Human

Botulism in the United States and Canada."

THE COURT: We've got it, too?

Q Which is a tabulation of reported cses from 1899 through 1964 prepared by Meyer and Eddie.

I ask you if you are familiar with this?

A Yes, I am.

Q Is that a recognized and accepted authoritative work in the field?

A Dr. K. F. Meyers is probably one of the most outstanding researchers in -- Dr. Meyers is considered and was considered the most outstanding researcher in clostridium botulinom.

Q Let me direct your attention to Pages 63 through 65 of that work.

THE COURT: Sixty-three?

MR. EINSTEIN: 63 and 64 of that work.

Q Do those pages summarize the total outbreaks of botulism illness during the period covered by the work and break it down, break down those outbreaks as between commercial and home processed foods?

A Yes --

MR. MC MORROW: Objection. This is totally irrelevant.

THE COURT: I'm not sure you don't want

it in evidence.

MR. MC MORROW: I fail to see it's relevancy, your Honor.

THE COURT: I take it what we're talking about are reported outbreaks?

MR. EINSTEIN: Correct.

THE WITNESS: Reported and also documented outbreaks, confirmed outbreaks.

THE COURT: We;re not going back to a plague year or any type of that material.

Q Is it eighteen --

MR. EINSTEIN: It's 1899 through 1964, your Honor.

THE COURT: What are they, are they limited to the whiteful context of fish --

MR. EINSTEIN: Total outbreaks and the table that I direct his attention to shows the total number of reported outbreaks and breaks it down as between commercially processed foods of all kings and home processed foods.

THE COURT: Whatever that means.

MR. EINSTEIN: That means when my wife or yours cans some food in the kitchen.

THE COURT: Maybe we better look at the figures

together.

MR. MC MORROW: Your Honor --

THE COURT: I take it this really is saying how bad is the whole botulism business anyway.

MR. EINSTEIN: That's exactly it, your Honor.

THE COURT: In other words, whether the public terror which the name of the very word conjures up has a foundation in nistorical experience.

MR. EINSTEIN: That's correct.

MR. MC MORROW: We submit, your Honor, that that consideration is irrelevant in the proceeding before this Court.

THE COURT: I'm inclined to think so, but knowing the human mind as little as I do, I can't bet that one of those three judges isn't going to swear if he doesn't find that fascinating statistics somewhere in the record, whether he thinks it's relevant or not, to satisfy his basic inquisitiveness.

BY MR. EINSTEIN:

Q Can you tell us then from the tables on Pages 63 --

THE COURT: I think we ought to mark the

table.

MR. EINSTEIN: I'd be glad to do that.

The new rule, again, your Honor, provides for the reading into the record in evidence of learned treatises relied upon by experts.

THE COURT: This comes under statistics, I think.

MR. EINSTEIN: This --

THE COURT: This doesn't purport to teach. This purports to be a record of event and comes in pretty much on the same basis of stock quotations in the Wall Street Journal.

MR. EINSTEIN: I will offer the publication in evidence.

THE COURT: Not the publication.

MR. EINSTEIN: The table?

THE COURT: The table is all we're talking about.

MR. EINSTEIN: I will offer in evidence then Pages 63 and 64 of the Meyers and Eddie book, "Sixty-Five Years of Human Botulism in the United States and Canada."

THE COURT: Will will Xerox that.

MR. MC MORROW: I object, your Honor. It's

totally irrelevant.

THE COURT: Objection overruled.

THE CLERK: So marked Defendant's P in Evidence.

(So marked.)

BY MR. EINSTEIN:

Q Dr. Eklund, for our benefit, can you tell us by examining the table which has been marked Defendant's P in Evidence, the total number of outbreaks of botulism shown in that table?

(Handing.)

MR. MC MORROW: Objection.

Q Since 1899 --

THE COURT: It's in evidence now.

A 651 outbreaks.

Q How many of those have resulted from commercial processing?

A Commercial processing, 38 cases, outbreaks.

Q Would you look again? Isn't it 65 or am I improperly reading the table?

A Oh, yes, commercially canned -- this includes the total of 65 outbreaks.

Q Let me direct your attention, Dr. Eklund, to Pages 74 through 76 of that same publication.

Do those tables describe or break down the 65 commercial outbreaks?

A Yes, they do.

Q By date, state and food source, I believe?

A Right, that is correct.

MR. EINSTEIN: I would like to offer those pages into evidence. That will be Pages 74 through 76.

MR. MC MORROW: I object, your Honor. It is not relevant.

THE COURT: Let it be received as Exhibit P-1.

THE CLERK: So marked Defendant P-1.

(So marked.)

MR. EINSTEIN: Would your Honor want to see it?

THE COURT: I'll do that later.

BY MR. EINSTEIN:

Q By examining Exhibit P-1, constituting these three pages, can you tell us of the 65 commerical outbreaks how many of them resulted from processed whitefish?

A Eight of these outbreaks were from whitefish, but this table has listed whitefish, chubs, together with whitefish.

Q It could either be whitefish or chubs?

A Yes.

Q Eight of them relate to that kind of fish, either a chub or a whitefish?

A That's correct.

Q In what years were those outbreaks?

A The first outbreak was in 1960.

THE COURT: Six-oh?

THE WITNESS: 1960.

A (Continuing) The balance of these were in 1963.

Q Does that table also reveal anything concerning the manner in which the whitefish or chubs were packaged?

A Yes --

MR. MC MORROW: Objection.

A Vacuumed packaged.

Q Is there any indication of outbreaks in the table from whitefish that was not vacuumed packaged?

MR. MC MORROW: Your Honor, I object to the line of testimony. It's not relevant. Besides that --

THE COURT: This did precede the issuance of the regulation.

Whether the data had then been compiled or

not, I don't know. Have they been?

MR. MC MORROW: That is in the record in one form or another, the publication.

MR. EINSTEIN: The publication is not in the record.

THE COURT: If it is in the administrative record somewhere no harm is done here.

MR. MC MORROW: It serves no purpose for him to testify as to it here.

THE COURT: I'm sorry, sir?

MR. MC MORROW: It serves no purpose for him to testify --

THE COURT: Except it saves me wearing my thumbs thin trying to find it in the administrative record if it is relevant.

MR. EINSTEIN: I'm sorry, I've forgotten my last question.

THE COURT: None of these were vacuumed packaged?

THE WITNESS: They were all vacuumed packaged.

THE COURT: Not all the ones we're dealing with. I take it the regulation doesn't deal with it.

BY MR. EINSTEIN:

Q Just to clarify it, the eight outbreaks reported in that publication all relate to vacuumed packaged chubs or whitefish; correct?

A That's correct.

Q Do you know whether the whiteful industry now,including the defendants, vacummed packed any of their whitefish?

A No, they do not.

Q When did they abandon that practice?

A This was abandoned shortly after the 1963 outbreak.

Q Are you familiar, based upon your general work in the field, with the causes of the 1960 and 1963 outbreaks?

A Yes, I am.

Q Would you describe what those causes were?

A The 1963 outbreak was a result of gross mishandling.

By this I mean the product was shipped at ambient temperatures of 90 degrees Fahrenheit and remained at this temperature for approximately four to five days and these samples were vacummed packaged.

Q What is the effect of the 90 degree temperature?

Why is that significant?

MR. MC MORROW: Your Honor, I would like to ask the Court to note this material is in the record in one form or another.

I don't know if the witness' recollection or his knowledge from whatever source he acquired it is parallel to what is in the administrative record.

I don't know what his source of information is. I don't know how he acquired his familiarity with these outbreaks, but there is material in the record bearing upon these outbreaks and we submit the Court should be restricted to the record.

THE COURT: I take it that's reflected in the regulation in the temperature controls.

MR. EINSTEIN: Dr. Eklund's testimony is that the processed fish, after processing, was not refrigerated and kept at 90 degrees.

THE COURT: Yes, I know. I say that the regulation with which we're dealing pays close attention to matters of refrigeration.

Q Was it abusive handling, Dr. Eklund, that you refer to by a processor or by a consumer or how did it

occur, do you know?

MR. MC MORROW: Your Honor --

THE COURT: Usually blamed on the railroad.

MR. EINSTEIN: You have to hear it.

MR. MC MORROW: I would like to restate my objection on relevancy grounds.

MR. EINSTEIN: Your Honor's impression --

BY MR. EINSTEIN:

Q Go ahead.

A This was during shipment.

Q What happened to the fish during shipment?

A During shipment of this batch of smoked fish, they were held at eighty degrees -- excuse me -- 90 degrees. They were first packaged in dry ice, as I understand, in a furniture truck.

Enroute, the dry ice evaporated and from there it was incubated, so to speak, at 90 degrees Fahrenheit.

Q What is significant about the 90 degrees?

A Ninety degrees Fahrenheit is the optimum temperature in which the clostridium botulinium Type E will grow and produce in.

It will not grow at temperatures below 38 degrees Fahrenheit.

Q You also mentioned vacuum packaging.

How does that come into play in this matter?

A Vacuum packaging will extend the storage life of many food products, fish are -- which are included.

It will inhibit mold growth. Also a number of bacteria which produce abnormal flavors and oders.

Q The vacuum packaging does not inhibit the growth of the botulism spore?

A No.

Q The net effect of packaging would be to delay the spoilage of the product which might --

THE COURT: Manifest --

Q Manifest spoilage which might lead a consumer to throw it out and yet permit the germ to form a toxin --

A With this extended storage life, there is also extending a period of time for the -- this to grow and produce this toxin.

Q Are there various factors which bear upon the outgrowth of spores of the clostridium Botulinium?

A Yes.

MR. MC MORROW: Objection, this is scientific testimony as to going to the heart of the

GMP, scientific deliberations conducted by the agency.

This is the same sort of testimony that this Court found inappropriate earlier.

I don't think it should be allowed.

THE COURT: Objection sustained.

MR. EINSTEIN: May he answer as an offer of proof?

THE COURT: It will be taken as an offer of proof if it doesn't extend too far.

MR. EINSTEIN: He has about 10 or 11 factors, your Honor.

I could attempt to elicit them or I would prefer if he do it. I think it would be far more expedicious.

THE COURT: Why doesn't he answer it in one fell swoop, under the objection?

BY MR. EINSTEIN:

Q Why don't you tell us what the factors are?

A The factors that affects the growth of the organism are temperature, number of spores that are present, storage conditions --

THE COURT: What's that?

THE WITNESS: Storage condition.

A (Continuing) Whether or not chemicals such as sodium Choride or salts, nitrate, sodium nitrates, the (Ph)of the products and in general the composition of the products.

THE COURT: That's Ph, capital P, little h; is that it?

MR. EINSTEIN: Capital P, little h.

THE WITNESS: PH; big H.

Q Does the cleaning of the product also have an effect?

A The cleaaning of the product, generally sanitation and eaven the use of in-plant coronation has been shown to greatly reduce the number of the spores, of course, which would be entered into the number of spores that would be involved in the growth.

Q Would the storeage time also have an effect?

A Yes, storage time and temperature.

THE COURT: And what?

THE WITNESS: Storage time and temperature.

Q How about the moisture content?

A Moisture content also plays a very important role.

Q In the presence of other bacteria?

A It would.

Q As an interrelationship, I gather if heat, smoke, salt and nitrates that all comes into balance?

A This plays a very important role. This is one of the successors today for the safety of pure bred meats, namely the use of nitrates.

MR. MC MORROW: I want the record to reflect I object to the entire line of testimony.

THE COURT: Yes, these are taken solely as an offer of proof.

Q Dr. Eklund, you mentioned before that the botulism spores will not grow below 38 degrees; is that correct?

A That's correct, this is only Type E.

Type A will not grow below 50 degrees Fahrenheit.

Q You mentioned Type E and then you mentioned Type A.

Would you describe to the Court the differences between the two types?

MR. MC MORROW: Objection, your Honor.

This testimony is irrelevant because the regulations themselves only purport to deal with the prevention of clostridium botulinium Type E, manifested in the preamble of the regulation and we again

are getting into the same line of scientific testimony that you found objectionable.

I think for both those reasons this line of testimony should not be allowed.

MR. EINSTEIN: Let me ask one question.

MR. MC MORROW: I would like a ruling.

MR. EINSTEIN: I will withdraw the question and ask another question.

THE COURT: That's what I understood him to mean.

BY MR. EINSTEIN:

Q Is your opinion of the processing parameters of the GMP effective against Type A botulism?

A No, they're not.

MR. MC MORROW: Objection.

THE COURT: Objection sustained, and the answer is received as an offer of proof.

Q Now, there is an effect of temperature on the outgrowth of the spores; is that correct?

A Yes, that's correct.

Q The more you raise the temperature, the quicker the spores will outgrow; is that correct?

A Yes --

THE COURT: Up to a point?

THE WITNESS: Up to a point; this is correct, sir.

Q Has some work been done based upon a spore-load of a million spores at an optimum, in an optimum growth medium in a laboratory?

A Yes, this has been done.

Q With this million spores at an optimum growth medium, at 38 degrees Fahrenheit, at what point would you get outgrowth?

MR. MC MORROW: Objection, your Honor. This is material being considered --

THE COURT: In the first place, it doesn't say what type of spores.

MR. EINSTEIN: Type E, referring only to Type E, your Honor.

A Yes, the minimum temperature --

MR. MC MORROW: Excuse me. My objection --

THE COURT: Objection sustained, received only as an offer of proof.

A Yes, at 38 degrees Fahrenheit growth and toxin productions produced by a million spores.

THE COURT: What?

THE WITNESS: As produced by the Type E organism.

Q In how many days?

A This will vary with a different strain of Type E used.

Q Approximately?

A This would probably be in the neighborhood of around 30 to 38 days, I would say.

MR. MC MORROW: I move to strike the answer as being irrelevant.

THE COURT: Motion granted.

The answer is taken as an offer of proof, not quite sure I understand it.

Were you saying that a million E spores, that optimum growth conditions other than temperature if maintained at 38 degrees temperature will nevertheless result in growth of spores and toxin and the production of toxins?

THE WITNESS: This is correct.

THE COURT: And did you say at a rate --

THE WITNESS: Yes, this will vary according to which strain of Type E is used, that in general this will be, I would say, 30 to 38 days probably is a good figure.

Q Will the time be longer in a fish?

A In a fish with salt, yes.

MR. MC MORROW: Objection, the same reasons as before.

Q How about in a fish without salt?

A In a fish without any sals, I would say this would be a very close optimum.

MR. MC MORROW: Excuse me. I want the record to reflect, your Honor, I move to strike the answer as being irrelevant.

I'm sorry. I have to keep interrupting.

I want the record to reflect this scientific testimony is being objected to.

THE COURT: That's perfectly clear.

The motion is granted. The evidence is taken solely as an offer of proof and not in relevance to the case.

Q Are you currently engaging in some work preparing fish at a hundred sixty degrees --

MR. MC MORROW: Objection, relevancy.

A I think now we're getting too far afied.

MR. EINSTEIN: I'm trying -- I'm now very clearly and admittedly in the de novo area.

THE COURT: That's not going to happen under any circumstances.

MR. EINSTEIN: I'm also trying to show that

since the passage of the GMP, there have been a great deal of scientific learning which should be brought to bear in this circumstance.

There are authorities, your Honor, which would indicate that the Court has the authority to consider the new scientific evidence.

MR. MC MORROW: The new scientific evidence, the Government welcomes it.

It would be delighted if Mr. Eklund and anybody else, that Mr. Einstein can produce, would submit this evidence to the FDA.

That is the first forum where it should be heard. In this Court it should not sit as the determiner of scientific evidence.

THE COURT: We have had the practical evidence here yesterday, men working in-field as producers and distributors of the product.

We will not need this.

MR. EINSTEIN: Might I ask Dr. Eklund to describe his current works as an offer of proof?

THE COURT: What?

MR. EINSTEIN: As an offer of proof.

THE COURT: No, we are getting too far afield. I think that what Dr. Eklund has said and

what he would prove has been adequately shown thus far.

To extend it is simply to cloud the record.

MR. EINSTEIN: I would like to make a formal offer for preserving the record, your Honor.

THE COURT: Proceed.

MR. EINSTEIN: I think I'm required --

THE COURT: Go ahead.

MR. EINSTEIN: I offer to prove, your Honor, that in hot smoked whitefish cooked at a temperature of 160 degrees Fahrenheit and then innoculated with spores ranging from zero through 10,000 spores, that after a period of incubation for seven days at optimum growth conditions, no spores were found in fish with a 3.0 salt level with a hundred spores per gram, but that - - excuse me. I can't read this.

(Mr. Einstein approached the witness.)

MR. EINSTEIN: But that toxins were shown in fish with 1,000 and ten thousand spores per gram and that in fish with salt levels of 3.5 per cent and higher, there was no toxin production in any of the fish including fish at spore levels of zero, one, ten, a hundred, 1,000 and 10,000 spores per

gram.

MR. MC MORROW: Your Honor, I object to that even as an offer of proof.

I think it is so far afield that even under the liberal approach that this Court has been take n with respect to compiling the record, it really doesn't belong here.

B fls.

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THE COURT: Yes, indeed, I think we are just going far beyond the necessity of propriety in the case.

MR. MC MORROW: There is no basis for this evidence, and there ought not to be any for this evidence. And it just ought not to be here.

BY MR. EINSTEIN:

Q Now, Dr. Eklund, are you aware of any scientific studies or work with respect to brining a fish?

A To the brining the fish? Can you elaborate a little more?

Q The soaking of the fish in the salt solution to get salt intake?

A Yes, I am familiar with the general studies that have been done.

Q Can you enumerate for us the factors which control the salt intake in a fish?

MR. MC MORROW: Objection.

Q In the process of brining?

THE COURT: I think this is going far too far.

MR. EINSTEIN: All right. I am only offering proof here, your Honor, that there are numerous and complex factors involved in the brining of fish, including the concentration of the brine, the length

of contact between the fish and the brine.

THE COURT: Isn't that all self-evident?

MR. EINSTEIN: They weren't to me until it was explained to me, your Honor.

THE COURT: Well --

MR.EINSTEIN: Whether the fish is fresh or frozen, the temperature of the brine, the fat content and other characteristics of the fish, the size of the fish, among other things, and the purpose being --

THE COURT: What?

MR. EINSTEIN: The size of the fish.

THE COURT: S-i-z-e?

MR. EINSTEIN: Yes. The purpose being to demonstrate that brining is a very inexact art rather than a science and a most difficult thing to achieve with any certainty in a commercial manufacturing plant.

MR. MC MORROW: Your Honor, I strongly object. These factors have been given due consideration, due deference.

THE COURT: It might be so. But people have been eating salt foods for I guess 10,000 years. I guess everybody knows that every bit of salt or anything else is a little bit different from every other one.

Q Now, Dr. Eklund, I show you a document dated March 11th, 1964 prepared by Mr. Castell of the Fisheries Research Board of Canada, called the report to the fishing industry on the significance of botulitumism in the Canadian fisheries.

THE COURT: The date?

MR. EINSTEIN: March 11, 1964, your Honor.

Q Is Mr. Castell a recognized expert in this field?

A Mr. Castell is well known in Canada for his work in micro-biology, yes.

Q Have you had occasion to examine this work?

A I have read this. Yes.

Q Have you had occasion to read the material, starting with the second full paragraph on the right-hand column of Page 10, and down through the conclusion at the bottom of Page 10?

A Yes, I have.

MR. EINSTEIN: I will ask that that portion of the report be marked for identification.
I will draw a line starting at the point where I directed his attention.

THE CLERK: So marked Defendant's Exhibit Q for identification.

Q Now, I would like to read you the material that is here and I'll ask you whether you agree or disagree with the conclusion reached by Mr. Castell in this treatise.

MR. MC MORROW: I object to this line of questioning. We are going far beyond --

THE COURT: Was that cited in the administrative record?

MR. EINSTEIN: No sir, it is not.

MR. MC MORROW: It doesn't sound familiar to me.

MR. EINSTEIN: It is not.

THE COURT: It is not in any of these bibliographies in here?

MR. EINSTEIN: No, sir.

MR. MC MORROW: Your Honor, it's been pointed out to me it may be referred to or cited in another article.

MR. EINSTEIN: Well, it is not included as one of the tabs.

MR. MC MORROW: A good deal of the work that was done in that is in the administrative record.

THE COURT: You see, I mean, how does it come before us?

MR. EINSTEIN: There is a conclusion here by

Mr. Castell as to the causes of botulitumism and as to the significance of any health hazards. It is that fact that I wish to bring before the Court.

THE COURT: I think there is a time and place for his opinion to have been brought forward and it was not. And it is excluded.

MR. EINSTEIN: All right. I will -- rather than read this, I will offer it in evidence.

THE COURT: Yes. Well, it's marked as Exhibit Q for identification.

MR. MC MORROW: I would like my objection noted for the record.

THE COURT: Yes. And the objection is sustained.

MR. EINSTEIN: I think, your Honor, I would like to amend my offer to include the entire booklet rather than simply the --

THE COURT: It doesn't change the ruling.

MR. EINSTEIN: I know it doesn't, but I think for the sake of completeness it would be better.

I have no further questions Dr. Eklund.

THE COURT: All right. We'll recess now until 2:20.

(Luncheon recess taken.)

DDS:jk
lpm

AFTERNOON SESSION
(2:20 p.m.)

(The following occurred at 2:25 o'clock p.m.)

DR. MELVIN EKLUND, called as a witness, having been previously duly sworn, resumed the stand and testified further as follows:

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Dr. Eklund, you testified on direct examination that I believe in excess of twenty per cent of the fish which you sampled from Lake Winnipeg contained these spores, is that correct?

THE COURT: Pardon?

MR. MC MORROW: In excess of twenty per cent of the fish which he took from Lake Winnipeg and examined indicated the presence of clostridium botulism type E.

THE WITNESS: That is correct.

Q And how many fish did you sample from the Great Slave Lakes?

A The Great Slave Lakes we sampled thirty-one.

Q Did you find the presence of the spore in any of those thirty-one?

A No, we did not.

Q Now, is the total number of your analyses thirty-one?

A No, forty-nine was the total of our analyses between Lake -- a combination of Lake Winnipeg and Great Slave Lake.

Q When did you collect these specimens of fish that you analyzed?

A These fish I received from a processor in California who also has the Great Slave Lake and Winnipeg fish sent to him. These were processed -- excuse me -- these were eviscerated, and frozen, and ready for thawing and brining, and smoking.

Q I see. And the fish which were given to you purported to be from Lake Winnipeg and Great Slave Lake --

A As I understand it, the original cartons -- these samples were in the original cartons as they were received from Canada and had -- were either Great Slave Lake or Lake Winnipeg stamped on them.

Q So you don't know where in the Great Slave Lakes those fish came from?

A At the present time I don't. But I had made arrangements for further studies on this when the ice melts.

Q Did you analyze samples of any other fish from the Great Slave Lakes?

A Not at this time, no.

Q In other words, so you have only done the one

sample of the 31; is that correct?

A Yes, 31, that is correct.

Q When did you conduct this analysis?

A This analysis was done approximately three, four weeks ago.

Q So you haven't had occasion to conduct, I believe, what would be characterized as a scientific analysis of the presence of the spore?

MR. EINSTEIN: Objection. I think he is characterizing it. I think if he wants to ask him whether it was a scientific investigation that he conducted --

THE COURT: Was it considered a scientific sampling?

THE WITNESS: This is the beginning of our scientific sampling. We will do further samples without question.

Q But would you consider your one analysis of the thirty-one fish from the Great Slave Lakes to be a scientific analysis?

A Yes, to the extent we have done it, yes.

Q With respect to indicating conclusively whether or not the spore exists in the Great Slave Lakes?

A I would say this, because of the absence of the -- I only looked at eighteen fish from Lake Winnipeg. Since we

found positive samples we didn't do anything further with this particular lake. So when we do find negative analysis we do go further. We also have taken spores of Type E, approximately ten spores, and seeded it into different samples to determine whether or not the fish or other microorganisms present would cause inhibition. It did not. So our detection limits -- our detection limits of the spores would be --

Q I believe you haven't fully responded to my question. Let me pursue it further. Since your results to date have been negative you stated that you are going to go further in your analyses?

A That is correct.

Q Will that involve collecting several samples over various periods of time?

A Yes, as well as making arrangements with the people who are at Great Slave Lake to collect samples, or perhaps we will do this ourselves to make sure they are asceptically collected. And we will determine mud samples -- we will be looking at mud samples plus uneviscerated fish and the eviscerated fish.

Q So it is quite possible that the results of your further examination -- or it is possible that the results of your further analyses will indicate the presence of the spore?

A It very well could. But the purpose of it is to get some idea or rough estimate of how many fish would contain one or more spores.

Q Isn't it possible that one of those thirty-one fish at another time, if it were caught at another time or at another place in the Lake, might contain the spore?

A This is true. But there has been very little work done on the Great Slave Lake, so we don't even know what the extent of the contamination is.

Q Is it correct to state that the studies, the scientific work to date have indicated that the C botulinum type E is rather ubiquitous?

A Yes, especially in the more northern hemisphere.

Q In fact, haven't you conducted instant studies yourself?

A Yes, I have.

Q Where were these studies conducted?

A My studies were conducted on the Pacific Coast of the United States reaching from Alaska all the way to the Mexican border.

Q Did you conduct any studies of fresh waters?

A Yes, we also studied Lake Washington, which is in Seattle, and the Colombia River.

Q What were the results of those studies?

A We did find them present --

Q Are you familiar with the work of Dr. Dolman?

A Yes, I am.

Q Has Dr. Dolman done incidence studies in Canada, in Canadian waters?

A Yes.

Q Has he, too, found type E to be ubiquitous in Canadian waters?

A In general he has. He has also found areas where he didn't find it. I think it is more the methodology used.

Q But you state that it is very prevalent or predominant in the Northern Hemisphere?

A Yes, I would say it is present in the Northern Hemisphere. No question.

Q Now, you expressed some familiarity with the 1963 outbreaks?

A Yes.

Q And I believe you stated that all these outbreaks involve vacuum-packed fish?

A According to the records, they do, yes.

Q Are you familiar with the outbreak which occurred in Kalamazoo, Michigan?

A That one was in question, I realize that.

According to the records of sixty-five years of botulism -- according to the KF Myers records on the sixty-five years of botulism they are all listed as vacuum-packed. I realize that in the other reports that there were some questions exactly as to how the fish was handled --

THE COURT: Exactly as to what?

THE WITNESS: How the fish was packaged or handled.

Q In other words, there was some question as to whether or not the Kalamazoo fish --

A That is one exception, right.

Q Is it your understanding based upon conversations with scientists who familiarize themselves with the '63 outbreak that it involves a whole smoked whitefish?

A Pardon me? I am sorry.

Q Did that incident involve a whole smoked whitefish?

A Which one? The Kalamazoo?

Q Yes, the Kalamazoo.

A Yes. As I recall it, I think -- I will have to clarify it. I am not positive whether it was that or it was in chunks.

Q Have you been led to understand or is it your understanding that that particular whitefish was not vacuum-packed?

A The Kalamazoo?

Q Yes.

A There was a question about it, as far as my understanding, about how it was actually packaged prior to purchase by the man and his wife.

Q Now, you stated that most of the spores which you found -- most of the spores which are found in or on fish, that is, the spores of type E, are in the viscera or on the surface of the fish?

A Yes, I would say that --

THE COURT: No, the intestine.

THE WITNESS: I said the intestinal tract. I would say in the viscera in general, yes, this is true.

And I qualify this by saying that earlier studies have generally shown that live animal tissue is sterile.

Q Are you aware of any scientific evidence that spores are not present within the flesh of the fish itself?

THE COURT: Within the --

Q (Continuing) Within the flesh of the fish itself?

A No, I am not.

Q Isn't it possible, Dr. Eklund, that spores which are in the intestines can get into the fish, into the flesh of the fish, during the evisceration operation?

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A This is true.

Q Isn't it possible that the spores can get into the fish in fact during the first stage of the catching of the fish in the lake through sportsman's devices, through hooks and devices like that?

A Yes, this is true. But when it does happen you also open up a pathway for high salt concentration in this area.

Q But it still causes a spore to get within the fish?

A It could, yes.

Q So you could have a very sharp instrument which would make a small, very small penetration into the skin, which would cause the spore to get into the flesh?

A Right. And you also open up pathways for high concentrations of salt in this area.

Q But the spore itself is fairly tiny; is it not?

A Yes.

Q It is microscopic; is that correct?

A But it is much bigger than the salt molecule.

Q The spore is what? Pardon me?

A It is much bigger than the salt molecule.

Q Incidentally, were you asked to analyze the fish from the Great Slave Lakes in connection with this proceeding?

A No, Mr. Einstein asked me if there was any incident in the Great Slave Lake. I thought it was an excellent suggestion. And so I also went ahead and I ordered the fish to be analyzed from the New York Smokers. This was my suggestion.

MR. MC MORROW: That is the extent of our cross-examination, your Honor.

The matters addressed by Dr. Eklund in his testimony which was -- which we objected to and which was sustained, and which was submitted as offers of proof -- we do not propose to ask any questions regarding. We believe that that is adequately dealt with by the Agency in the administrative record.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Eklund, do you have any personal knowledge or have there been any studies done to show whether in evisceration the intestine is pierced and then the flesh is pierced?

A As far as the entry or source of entry is concerned?

Q Well, is there -- I will rephrase it. Mr. McMorrow deposited what seemed to me to be a hypothetical question that if in evisceration you got a piercing of the

wall couldn't the spore enter?

Do you know whether in fact whether it does occur?

A No, I do not.

Q Has there been any work or studies on that at all?

A Not as far as showing penetration of the botulism spore, not that I recall.

MR. EINSTEIN: Thank you.

THE COURT: You may step down.

(Witness excused.)

MR. EINSTEIN: The defendant rests, your Honor.

MR. MC MORROW: The Government rests, your Honor.

(continued next page)

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MR. MC MORROW: The Government rests, your Honor.

THE COURT: Without more?

MR. MC MORROW: Excuse me?

THE COURT: I say, without more?

MR. MC MORROW: Yes, your Honor.

THE COURT: Maybe you can see where that leaves us, gentlemen.

MR. EINSTEIN: Your Honor, we would like some time to receive the transcript and submit a post-trial brief. I assume the Government would like to do the same. We, of course, renew our motions.

THE COURT: That's of course what I meant to ask the Government.

MR. EINSTEIN: We renew our motions to dismiss.

THE COURT: Yes.

MR. EINSTEIN:Make all the appropriate motions at the end of the case.

THE COURT: You move for an injunction.

MR. MC MORROW: Yes, your Honor, we do.

MR. EINSTEIN: I would appreciate having 30 days after receipt of the transcript to submit our briefs.

THE COURT: Well, some have been prepared; haven't they?

MR. EINSTEIN: Just the first day, your Honor.

THE COURT: When was that?

MR. EINSTEIN: Monday.

THE COURT: And then there is yesterday and today.

MR. MC MORROW: Yes, sir. That purports to be daily copy, but we just got Monday's.

THE COURT: That is the best they can do.

MR. MC MORROW: I find no fault, your Honor. The Court Reporters deem to do a good job.

THE COURT: Well, what do you think of that as a briefing schedule.

MR. MC MORROW: Well, are we anticipating reply briefs as well?

THE COURT: Well, take it -- you see, you have already put in memorandums as they have, and other material, so I suppose the next question is whether you think that at this stage, if anything further is necessary on your side or whether you're content with your submissions thus far, and we think you need only to reply to what they may have served.

MR. MC MORROW: Let me confer one moment with my colleagues.

THE COURT: Yes. Sure. Mr. Morey, I have

your copy of this. Do you want to make the supreme sacrifice?

MR. MOREY: I can get more, your Honor, if it will be any assistance to you.

THE COURT: They are very convenient and hard to come by. May I have it?

MR. MOREY: Yes, sir.

THE COURT: You have a copy of this modus compendium.

MR. EINSTEIN: Yes, I do, your Honor.

MR. MC MORROW: We are going to prepare and submit a supplemental memorandum, your Honor, tying all the arguments we have raised to date. To the facts, to the extent that the defendant proposes to challenge the regulations in the sense they are going to argue that the regulations -- I'm sorry, that the material which is in the administrative record is not on its -- that it's not on its face support the regulations. I think we can therein the posture challenge that, and we should have an opportunity to reply to that.

THE COURT: What would you think about 30 days, you would each have an extra submission, and any appropriate reply, say two weeks after that, or what?

MR. EINSTEIN: Yes.

4 MR. MC MORROW: I guess our concern, your Honor, is the fact that this is our concern that this is an injunction action.

THE COURT: Well, the only thing that both sides can rush to say is it's going on for the best part of five years, which isn't very good, but you see, the difficulty with -- my real question is whether the month is essential. But I have to play fair, too. I am planning to leave the country on May 27th, and I won't be back until June 14th. So I can't fake you people out, and I can't in conscience decide it before I leave.

MR. MC MORROW: Your Honor, the 30 days --

THE COURT: So that would, in effect, deny the defendants an opportunity to put in their argument in full form in the light of the record made. Now, I don't want you to believe that I expect to be persuaded, because thus far I am inclined to think that the Government's probably in the right, and that if they are not, they are wrong on something which is quite possibly not remediable in this court, and quite probably not remediable in this court. Now, I do see the point that there is, as always, in these cases, a question about what kind of regulation or authority has been delegated. This time it doesn't

come up in a clearcut way in which it does come up say, under the Internal Revenue Code, whether you have a reasonably clear contrast between -- for lack of better terminology, one can call constitutive regulations, and those regulations which are intended to translate the law into understandable English. Very important for the tax law.

Now, I think here the possibility that this is a -- merely an interpretive regulation, in the sense it could not be the foundation for mandatory relief. It is rather small, and I think if it is a question in which the regulation has a mandatory role, it would be rather difficult to say that it was not a set of regulations that was very close to the very center of the FDA expertise, and therefore in the area in which judicial scrutiny beyond, making sure that no one has gone off the deep end, acting abusive of authority or arbitrarily or without any records to support. The tribunal would first decide it as the one that must be thought of as the real law formation authority here in specific application.

Now, the fact that the FDA doesn't always put its most persuasive face up front, they seem very difficult to deal with. You can't get them to

6 talk. You can't get them to show you anything. It would be hard to work with, and doesn't help. But, here I think we have a problem with defining the record, and you point out, but I am not too sure of what kind of record support is requisite for action of this kind in the absence of what might be called record as support for a negation of the action. Let me see if I can put it in different context.

Maybe it will be a little different. You, gentlemen, I hope have never heard of the diapulse case. You see, this was a case where a man thought perhaps in entire good faith that there is a lot to the idea that if you can get very high frequency of electro-magnetic wave impulses into deep human flesh, it would be very great influence on the functions of the human system, and produce a wide range of curative effects.

Well, the very concept of this electro-magnetic intrusion that involved them in making necessarily broad claims, because if he was right about his central theory, then it was a cure for everything. Because it stimulated the central nervous system, and all that kind of stuff.

Well, people have been keeping away at this idea from the time of the magnetic healers

7 in the last century right down through the turn of the century, right down to date. Nobody has really been able to come up with satisfactory clinical data yet, and so the FDA has never felt agreeable to go along with it, particularly when it's put forward in any specificity of claim. You see, there is a case where in a way it wasn't up to the FDA to show that you couldn't heal anything with this machine, because it was up to the machine to see that it could, and the total absence of truly controlled tests, now double lined this, that the next thing you have would be controls -- that was enough to really to damn the machine. Now, I think maybe we are a little bit in that area. If you have the ocean presence of C botulitum Type E, then the question is at what levels can you be sure it's at. Fresh fish -- fresh white fish, cuts expensively to the market. I suppose frozen can be bought in some fish stores, if you want to pay that much, if you are a fish fancier, and then let out even more botulitum Type E, theoretically, but they did not, subject to FDA regulations. I guess agriculture takes care of that. Don't they take care of meat and fish; raw fish. And anyway, most people don't eat their fish raw, they cook it. By that time the

8 botulitum, would have their goose cooked, we hope. It's like the even more deadly stuff, I guess that's in uncooked pork. So, this may be to the extent that sort of case of how do you give to the Department the insurance that will enable it, the administration enable it to say, "Okay. Boom ahead, distribute, and we won't regard it as adulterated."

Once their attention is drawn to the area, I think that is a bit of a problem, and to say that they hadn't demonstrated that these fish are unsafe, which is in a way what you contain to mean, is that they are not, isn't enough. You have to have perhaps have satisfied the minimum that the risk has been excluded, and that may be part of the whole problem here.

Now, it may well be, as Dr. Eklund has said, that these botulitum Type E are rare, are as rare as diamonds, but they don't have a good reputation if they do escape into the toxic stage, as I suppose they can get into the average inadequate home refrigerator.

(Continued on next page)

JB/LH 3/1

THE COURT: Now, that could become serious, I expect.

All right. Anyway, you may want to think about it. And if I am dead wrong about that, make sure that I am satisfied I am dead wrong about it.

Okay.

MR. EINSTEIN: Your Honor, I think Mr. McMorrow and I are in agreement that it will be June 21st for the main briefs and July 2nd for reply briefs, that that would be reasonable.

MR. MC MORROW: That is satisfactory.

MR. EINSTEIN: You don't want to go over to the July 4th weekend?

MR. MC MORROW: Please.

MR. EINSTEIN: All right. Let's do it for the 2nd. That's a Friday.

MR. MC MORROW: Thank you.

MR. EINSTEIN: Thank you, your Honor, for your patience.

THE COURT: All right.

(At this time, the case was concluded.)

I N D E X

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DR. MELVIN EKLUND	461	531		

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PLAINTIFF'S EXHIBIT 1 - PAGES FROM 10/23/69 FEDERAL REGISTER - PROPOSED REGULATION

FEDERAL REGISTER

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Thursday, October 23, 1969 • Washington, D.C.

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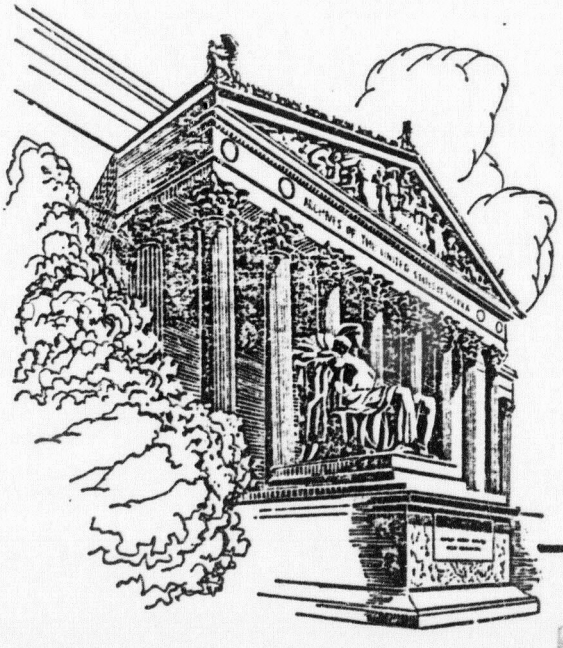

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acreage allotments for new farms, which are farms on which tobacco was not produced or considered produced during the immediately preceding 5 years. The part of the reserve held for apportionment to new farms shall be allotted on the basis of land, labor, and equipment available for the production of tobacco, crop rotation practices, soil and other physical factors affecting the production of tobacco and the past tobacco-producing experience of the farm operator. The farm yield for any farm for which a new farm acreage allotment is established shall be determined on the basis of available productivity data for the land involved and farm yields for similar farms, and shall not exceed the community average yield."

Section 317(f) provides: "Only the provisions of the last two sentences of subsection (g) of section 313 of this Act shall apply with respect to acreage-poundage programs established under this section. The acreage reductions required under the last two sentences shall be in addition to any other adjustments made pursuant to this section, and when acreage reductions are made the farm marketing quota shall be reduced to reflect such reductions. The provisions of the next to the last sentence of such subsection pertaining to the filing of any false report with respect to the acreage of tobacco grown on the farm shall be applicable to the filing of any false report with respect to the production or marketings of tobacco grown on a farm for which an acreage allotment and a farm yield are established as provided in this section. In establishing acreage allotments and farm yields for other farms owned by the owner displaced by acquisition of his land by any agency, as provided in section 378 of this Act, increases or decreases in such acreage allotments and farm yields as provided in this section shall be made on account of marketings below or in excess of the farm marketing quota for the farm acquired by the agency. * * *"

Flue-cured farm marketing quotas may be leased and transferred on a pound for pound basis, under the provisions of section 316, as amended (7 U.S.C. 1316).

The Act (7 U.S.C. 1301(b)) defines the "reserve supply level" of Flue-cured tobacco as the normal supply plus 5 per centum thereof. "Normal supply" is defined as a normal year's domestic consumption and exports, plus 175 per centum of a normal year's domestic consumption and 65 per centum of a normal year's exports. A "normal year's domestic consumption" is defined as the yearly average quantity produced in the United States and consumed in the United States during the 10 marketing years immediately preceding the marketing year in which such consumption is determined, adjusted for current trends in such consumption. A "normal year's exports" is defined as the yearly average quantity produced in the United States which was exported from the United States during the 10 marketing years immediately preceding the marketing year in which such exports are determined, adjusted for current trends in such exports.

The subjects and issues involved in the proposed determinations with respect to Flue-cured tobacco for the 1970–71 marketing year are:

1. The amount of the national marketing quota on an acreage-poundage basis.
2. The amount of the national average yield goal.
3. The amount of the national acreage allotment.
4. The amount of acreage to be reserved from the national acreage allotment for making corrections in farm acreage allotments, adjusting inequities, and for establishing acreage allotments for new farms.
5. The national acreage factor.
6. The national yield factor.

The community average yields, as computed in 1965 (30 F.R. 6207, 9875, 14487), will be used for the 1970–71 marketing year.

Consideration will be given to data, views, and recommendations pertaining to the proposed determinations, rules, and regulations covered by this notice which are submitted in writing to the Director, Tobacco Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture, Washington, D.C. 20250.

All written submissions made pursuant to this notice will be made available for public inspection at such times and places and in a manner convenient to the public business (7 CFR 1.27(b)). All submissions must, in order to be considered, be postmarked not later than 30 days from the date of publication of this notice in the FEDERAL REGISTER.

Signed at Washington, D.C. on October 13, 1969.

KENNETH E. FRICK,
Administrator, Agricultural Stabilization and Conservation Service.

[F.R. Doc. 69–12407; Filed, Oct. 22, 1969; 8:45 a.m.]

Consumer and Marketing Service

[7 CFR Part 907]

NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Notice of Extension of Time for Filing of Written Data, Views, or Arguments

Pursuant to the provisions of the marketing agreement, as amended, and Order No. 907, as amended (7 CFR Part 907), a notice of proposed rule making was published in the October 10, 1969, issue of the FEDERAL REGISTER (34 F.R. 15713) regarding amendments to the rules and regulations (Subpart—Rules and Regulations; §§ 907.100–908.142). Interested persons were afforded the opportunity to submit written data, views, or arguments not later than October 20, 1969.

A request for extension of time for submitting such comments has been made by the Navel Orange Administrative Committee to afford interested persons additional time to consider the proposal.

Notice is hereby given that the time for submitting written data, views, or arguments on the proposal is extended until October 30, 1969.

Dated: October 20, 1969.

PAUL A. NICHOLSON,
Acting Director, Fruit and Vegetable Division, Consumer and Marketing Service.

[F.R. Doc. 69–12689; Filed, Oct. 22, 1969; 8:49 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 128a]

HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING

Smoked Fish

Observation in smoked fish processing plants by the Food and Drug Administration and other regulatory agencies since 1963 has shown that the smoked fish industry has not consistently adhered to manufacturing practices that would minimize the hazard of Type E botulism and the risks of food-borne infections in the consumption of smoked fish.

The Bureau of Commercial Fisheries, Department of the Interior, has suggested that adequate times and temperatures along with salt concentrations have not yet been established for each individual species smoked other than smoked chub. The Bureau provided recommendations that proposed regulations be limited to plant sanitation, excluding reference to processing techniques that would (1) deal with time-temperature relationships or (2) describe good manufacturing techniques for smoked chub that would pertain only to smoked chub as processed in accordance with the food additive regulation § 121.1230 *Sodium nitrite used in processing smoked chub* (34 F.R. 13659).

The Food and Drug Administration acknowledges that adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked. Much work has been done, however, on the thermal destruction of spores of *Clostridium botulinum* Type E, and to date the processing parameters presented in the proposal are the safest known from the standpoint of preventing outgrowth and toxin formation of *C. botulinum* Type E. It has been established that the public health hazard of *C. botulinum*

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Type E in smoked fish is not restricted to a single species. Examples of species found to contain spores of *C. botulinum* Type E are lake trout, salmon, black cod (sablefish), sole, sturgeon, and whitefish.

The FDA has been, is, and will continue to be receptive to scientific data that documents adequate processing parameters or offers alternate processing parameters for any individual species of smoked fish. Data must be provided showing that the proposed processing parameters adequately minimize risks of the public health hazard of poisoning by Type E botulism.

Currently, the situation exists whereby some processors base their manufacturing practices solely on the appearance and acceptability of the finished product quality to consumers rather than on any specific or controlled processing parameters that would minimize the health hazard of *C. botulinum* Type E or its toxins.

Having considered the foregoing, the Commissioner of Food and Drugs proposes the following regulations setting forth specific manufacturing practice (sanitation) requirements regarding hot processed smoked fish.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that the following new Part 128a be added to Chapter I of Title 21:

PART 128a—FISH AND SEAFOOD PRODUCTS

Subpart A—Smoked Fish

Sec.

128a.1 Definitions.
128a.2 Current good manufacturing practice (sanitation).
128a.3 Plants and grounds.
128a.4 Equipment and utensils.
128a.5 Sanitary facilities and controls.
128a.6 Sanitary operations.
128a.7 Processes and controls.

AUTHORITY: The provisions of this Part 128a issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a).

§ 128a.1 Definitions.

(a) *Smoked fish.* As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the action of smoke from burning wood, sawdust, or similar material.

(b) *Loin muscle.* As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(c) *Water phase salt.* As used in this part, "water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method prescribed in the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th Edition, 1965, page 273, under paragraph 19.009, multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method prescribed under paragraph 18.006.

(d) *Hot process smoked fish.* As used in this part, "hot process smoked fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraph (a) of this section to heat to cook it. The finished hot process smoked product contains not less than 3½ percent salt (sodium chloride) in the water phase of the loin muscle as determined by the methods prescribed by paragraph (c) of this section. The food additive sodium nitrite may be used in accordance with the conditions prescribed by § 121.1230 of this chapter.

§ 128a.2 Current good manufacturing practice (sanitation).

(a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this Subpart A set forth additional requirements for the hot process smoked fish industry.

§ 128a.3 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Receiving or shipping.

(2) Storage of raw fish.

(3) Presmoking operations (thawing, dressing, brining, etc.).

(4) Drying and smoking.

(5) Cooling and packing.

(6) Storage of final product.

(c) The product shall be so processed as to prevent contamination by exposure to areas involved in earlier processing steps, refuse, or other objectionable areas.

§ 128a.4 Equipment and utensils.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature measuring devices shall have an accuracy of ±2° F.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store the fish shall not be nested or handled in a manner conducive to direct or indirect contamination of the contents.

(c) Adequate measures shall be taken when cleaning and sanitizing utensils and portable equipment to prevent this operation from leading to the contamination of fish or fish products.

§ 128a.7 Processes and controls.

(a) *Raw materials.* (1) Fresh fish shall be adequately washed and inspected to remove all fish that are filthy, putrid, decomposed, bruised, crushed or otherwise damaged.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish shall be chilled with ice or refrigerated to an internal temperature of 38° F. or below when received and shall be maintained at that temperature until the fish are to be processed.

(4) Frozen fish shall be received and stored at a temperature of 0° F. or below.

(b) *Defrosting of frozen fish.* (1) Frozen fish shall be defrosted:

(i) In air at 45° F. or below until other than hard frozen; or

(ii) In a continuous water overflow thaw tank or spray system using water not greater than 70° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are thawed.

(3) Fish entering the thaw tanks shall be free of packaging material.

(4) On removal from the thaw tank, fish shall be washed thoroughly with a vigorous water spray.

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(c) *Presmoking operation.* (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish shall be thoroughly washed by means of a continuous spray system.

(3) All fish shall be brined in a solution that does not exceed 38° F.

(4) Hot process smoked fish shall be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than 3.5 percent.

(5) Fish shall be rinsed with fresh water after brining.

(d) *Heating, cooking, smoking operation.* (1) A point-sensitive continuous temperature recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the smokehouse.

(2) Hot process smoked fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of 180° F. or above for a minimum of 30 minutes for hot process smoked fish, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section.

(e) *Packing.* (1) The finished product shall be handled only with clean, sanitized hands or gloves.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to 38° F. or below within 3 hours after smoking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F. or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks should show at least the date of packing and the plant where packed.

(f) *Testing.* (1) The microbiological condition of the firm's operation shall be evaluated by the periodic collection and analysis of in-line and finished product samples coupled with sample-related inspections. This evaluation should be made at least weekly and more often when problems are encountered.

(2) The finished product shall be examined for salt content with sufficient frequency to assure that the required salinity is obtained in every fish.

Any interested person may, within 30 days from the date of publication of this notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: October 16, 1969.

J. K. KIRK,
Associate Commissioner for Compliance.

[F.R. Doc. 69-12685; Filed, Oct. 22, 1969; 8:48 a.m.]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 69-EA-114]

TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering amending § 71.181 of Part 71 of the Federal Aviation Regulations so as to alter the Errol, N.H., 700-foot transition area (34 F.R. 9853).

With the promulgation of the U.S. Standard Terminal Instrument Procedures (TERPs) the criteria for instrument procedures was revised. This revision requires a change in the airspace of the transition area which is compatible with the new instrument criteria.

Interested persons may submit such written data or views as they may desire. Communications should be submitted in triplicate to the Director, Eastern Region, Attention: Chief, Air Traffic Division, Department of Transportation, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, N.Y. 11430. All communications received within 30 days after publication in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements may be made for informal conferences with Federal Aviation Administration officials by contacting the Chief, Airspace and Standards Branch, Eastern Region.

Any data or views presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Office of Regional Counsel, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, N.Y.

The Federal Aviation Administration, having completed a review of the airspace requirements for the terminal area of Errol, N.H., proposes the airspace action hereinafter set forth:

1. Amend § 71.181 of Part 71 of the Federal Aviation Regulations so as to delete in the description of the Errol, N.H., transition area, "within 2 miles" and insert "within 2.5 miles" in lieu thereof.

This amendment is proposed under section 307(a) of the Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348), and section 6(c) of the DOT Act (49 U.S.C. 1655(c)).

Issued in Jamaica, N.Y., on October 8, 1969.

WAYNE HENDERSHOT,
Acting Director, Eastern Region.

[F.R. Doc. 69-12668; Filed, Oct. 22, 1969; 8:47 a.m.]

[14 CFR Part 71]

[Airspace Docket No. 69-EA-107]

TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering amending § 71.181 of Part 71 of the Federal Aviation Regulations so as to alter the Skaneateles, N.Y. 700-foot transition area (34 F.R. 12027).

With the promulgation of the U.S. Standard Terminal Instrument Procedures (TERPs) the criteria for instrument procedures was revised. This revision requires a change in the airspace of the transition area which is compatible with the new instrument criteria.

Interested parties may submit such written data or views as they may desire. Communications should be submitted in triplicate to the Director, Eastern Region, Attention: Chief, Air Traffic Division, Department of Transportation, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, N.Y. 11430. All communications received within 30 days after publication in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements may be made for informal conferences with Federal Aviation Administration officials by contacting the Chief, Airspace and Standards Branch, Eastern Region.

Any data or views presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Office of Regional Counsel, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, N.Y.

The Federal Aviation Administration having completed a review of the airspace requirements for the terminal of Skaneateles, N.Y., proposes the airspace action hereinafter set forth:

1. Section 71.181 of Part 71 of the Federal Aviation Regulations so as to delete in the description of the Skaneateles, N.Y., transition area, "2 miles each side of the Syracuse VORTAC 215° radial", and all thereafter, and insert the following in lieu thereof, "3.5 miles each side of the Syracuse VORTAC 215° radial

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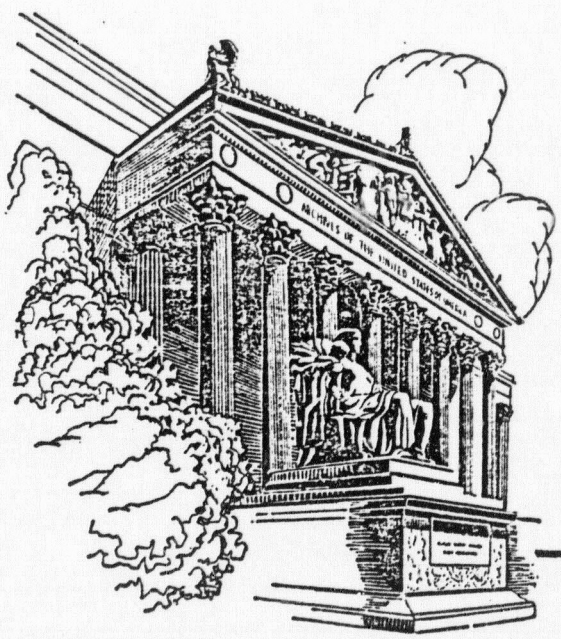
Interim Compliance Panel (Coal Mine Health and Safety)
Internal Revenue Service
Interstate Commerce Commission
Land Management Bureau
Manpower Administration
National Credit Union Administration
National Oceanic and Atmospheric Administration
Public Health Service
Securities and Exchange Commission
Small Business Administration
Social and Rehabilitation Service
Social Security Administration
Wage and Hour Division

Detailed list of Contents appears inside.



THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

PLAINTIFF'S EXHIBIT 2 - PAGES FROM 11/13/70 FEDERAL REGISTER - FINAL REGULATION

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 2.120), § 121.1082(b) is amended by adding a new subparagraph, as follows:

§ 121.1082 Modified hop extract.

* * * * *

(b) * * *

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, *n*-butyl alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of *n*-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in § 121.1203 except that the boiling point range for light petroleum spirits is 150° F. to 300° F.

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on its date of publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1))

Dated: November 3, 1970.

R. E. DUGGAN,
Acting Associate Commissioner for Compliance.

[F.R. Doc. 70-15268; Filed, Nov. 12, 1970; 8:46 a.m.]

PART 128a—FISH AND SEAFOOD PRODUCTS

Subpart A—Smoked and Smoke-Flavored Fish

Current good manufacturing practice (sanitation) in manufacture, processing, packing, or holding of smoked and smoke-flavored fish for human food.

In the FEDERAL REGISTER of October 23, 1969 (34 F.R. 17176), the Commissioner of Food and Drugs proposed regulations (Subpart A, Part 128a) covering current good manufacturing practice (sanitation) in the manufacture, processing, packing, or holding of smoked fish. In response, comments were received from two trade associations, eight manufacturers, and the Bureau of Commercial Fisheries, Department of Interior. The comments include opposition to certain requirements and suggestions for clarifying and technical changes.

The principal objection is that the process requirements in the proposed regulations cannot be applied to all species of fish presently being smoked by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis.

The Commissioner finds: (1) That although adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of *C. botulinum* Type E; and (2) that since the public health hazard of *C. botulinum* Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay.

Therefore, having considered the comments received and other relevant material, the Commissioner concludes that the proposed regulations, with most of the suggested clarifying and technical changes incorporated, should be adopted as set forth below. Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), the following new Subpart A is added to Part 128a:

Subpart A—Smoked and Smoke-Flavored Fish

Sec.
128a.1 Definitions.
128a.2 Current good manufacturing practice (sanitation).
128a.3 Plants and grounds.
128a.4 Equipment and utensils.
128a.5 Sanitary facilities and controls.
128a.6 Sanitary operations.
128a.7 Processes and controls.

AUTHORITY: The provisions of this Subpart A issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a).

§ 128a.1 Definitions.

(a) *Smoked fish.* As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.

(b) *Smoke-flavored fish.* As used in this part, the term "smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke. This paragraph does not alter the labeling requirements under § 3.201 of this chapter.

(c) *Loin muscle.* As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(d) *Water phase salt.* As used in this part, "Water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th edition, page 273 (1965), multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of said edition.

(e) *Hot-process smoked or hot-process smoke-flavored fish.* As used in this part "hot-process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraphs (a) and (b) of this section to heat as prescribed in § 128a.7(b).

§ 128a.2 Current good manufacturing practice (sanitation).

(a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this Subpart A set forth additional requirements for the hot-process smoked or hot-process smoke-flavored fish industry.

§ 128a.3 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes should be carried out in separate rooms or facilities, and the interior walls separating these processes should extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Receiving or shipping.

(2) Storage of raw fish.

(3) Presmoking operations (thawing, dressing, brining, etc.).

(4) Drying and smoking.

(c) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Cooling and packing.

(2) Storage of final product.

(d) The product shall be so processed as to prevent contamination by exposure to areas, utensils, or equipment involved

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in earlier processing steps, refuse, or other objectionable areas.

§ 128a.4 Equipment and utensils.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature-measuring devices shall have an accuracy of ±2° F.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents.

(c) Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

§ 128a.7 Processes and controls.

(a) *Raw materials.* (1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated to an internal temperature of 38° F. or below upon receipt and shall be maintained at that temperature until the fish are to be processed.

(4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.

(b) *Defrosting of frozen fish.* (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:

(i) In air at 45° F. or below until other than hard frozen; or

(ii) In air so that the temperature in any part of the fish does not exceed 45° F.; or

(iii) In a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are completely defrosted.

(3) Fish entering the thaw tanks shall be free of exterior packaging material and substantially free of liner material.

(4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.

(c) *Presmoking operation.* (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous water spray or a continuous waterflow system.

(3) All fish shall be brined in a solution that does not exceed 38° F. or dry-salted at a temperature not to exceed 38° F. throughout the fish.

(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a maner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d) (2) (i) of this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d) (2) (ii) of this section.

(5) Fish shall be rinsed with fresh water after brining.

(d) *Heating, cooking, smoking operation.* (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature threughout each fish of:

(i) Not less than 180° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (i) of this section, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (ii) of this section.

(e) *Packing.* (1) The finished product shall be handled only with clean, sanitized hands, gloves, or utensils.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to a temperature of 50° F. or below within 3 hours after cooking and further cooled to a temperature of 38° F. or below within 12 hours after cooking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F. or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify at least the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification (i) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish and (ii) of the distribution of the finished product.

(f) *Testing.* (1) Microbiological examination of in-line and finished product samples should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

(2) The finished product shall be analyzed chemically with sufficient frequency to assure that the required salinity is obtained in every fish and that other chemical additives are present at authorized levels.

Effective date. This order shall become effective 30 days after its date of publication in the FEDERAL REGISTER.

Dated: November 2, 1970.

SAM D. FINE,
Associate Commissioner for Compliance.

[F.R. Doc. 70-15269; Filed, Nov. 12, 1970; 8:46 a.m.]

SUBCHAPTER C—DRUGS

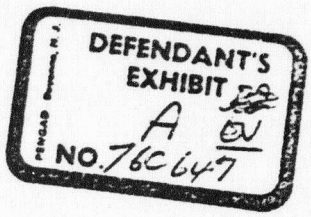
PART 148c—COLISTIN

Effective on publication in the FEDERAL REGISTER, Part 148c is republished as follows to incorporate editorial and

BEST COPY AVAILABLE

DEFENDANTS' EXHIBITS

DEFENDANTS' EXHIBIT A - LETTER DATED AUGUST 5, 1975
FROM DAVID SKLAR TO FOOD AND DRUG ADMINISTRATION



August 5, 1975

U. S. Food & Drug Administration
850 Third Avenue
Brooklyn, New York 11232

Gentlemen: Attention: Mr. Clarence Waltrums

We have further reference to our letter of July 14, 1975 in connection with the recent inspection in our plant by Investigator Diana J. Kolaitis.

A few days following the inspection, we had installed indicating thermometers on Freezer #5 and Refrigerator #9 so that we now can see from the outside of these cold boxes what the inside temperature is. (This refers to item #3 on the hand-written observation given to us by your inspectors.) All our refrigerators now have either recording thermometers and/or indicating thermometers.

We are looking forward to receiving the full report of the recent investigation so that we can direct our attention to those items that might need correction.

Cordially yours,

DAVID SKLAR?

DS/rs

DEFENDANTS' EXHIBIT B - LETTER DATED MAY 4, 1970 FROM THE ASSOCIATION OF SMOKED FISH PROCESSORS, INC. TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

Association of Smoked Fish Processors, Inc.

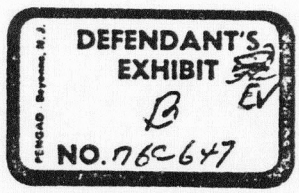
TECHNICAL CENTER

54 CLAYTON STREET
BOSTON, MASSACHUSETTS 02122

RECEIVED MAY

May 4, 1970

General Fred J. Delmore
U. S. Food and Drug Administration
Dept. Health, Education & Welfare
200 C Street, S.W.
Washington, D.C. 20204



Dear General Delmore:

The Association of Smoked Fish Processors, Inc., has reviewed the "Comments" submitted to you by letter from the National Fisheries Institute, Inc., dated April 28, 1970 and is in general agreement with their comments with few exceptions as noted below. To minimize repeating their comments, we will make reference only to the sections commented on and our agreement or modification of each.

COMMENTS

Page 2, lefthand column, second paragraph - same as NFI

Page 4, lefthand column, section 128a.1(b) - same as NFI

Page 4, lefthand column, section 128a.1(c) - same as NFI

Page 5, righthand column, section 128a.1(e) - same as NFI

Page 7, lefthand column, section 128a.3(b) - same as NFI

Page 9, lefthand column, section 128a.6(b) - same as NFI

Page 9, righthand column, section 128a.7(a)(1)-same as NFI

Page 10, lefthand column, section 128a.7(a)(3) - As proposed, this would require that all fresh or partially processed fish be received by the processor at an internal temperature of 38°F or below. Industry members pointed out that all such fish received simply will not always be at that low a temperature especially during the summer. While it is in the processors best interest to receive chilled and well-iced fish, it is recognized that at certain times the receiving temperature may not be as low as 38°F. The processor does not want to reject otherwise sound and wholesome fish solely because

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Page 10, lefthand column, section 128a.7(a)(3) - (continued)

of this strict temperature limitation. Accordingly, we would like to revise Section 128a.7(a)(3) to be as follows:

"(3) Upon receipt, fresh or partially processed fish, except those to be immediately processed, shall be chilled with ice or refrigerated to an internal temperature of 38°F or below and shall be maintained at that temperature until the fish are to be processed."

As we agreed, receiving temperature data is being collected by Association members and the FDA will be advised of our findings as soon as this information can be collected and compiled.

Page 10, lefthand column, section 128a.7(a)(4) - same as NFI

Page 11, lefthand column, section 128a.7(b)(2) - same as NFI

Page 12, righthand column, section 128a.7(b)(4) - same as NFI

Page 13, righthand column, section 128a.7(c)(3) - As proposed, this provision would require that all fish be brined in a solution that does not exceed 38°F. The Association feels, as they have previously commented, that section 128a.7(c)(3) should be revised as follows:

"(3) All fish shall be brined in a solution that does not exceed 50°F."

The reason for this proposed revision is not as indicated by the NFI comments regarding difficulties in attaining temperatures (the NFI comment is in error since ice, refrigerated water and pre-refrigeration storage are used to attain low brine temperature) but is based on the industry's desire to facilitate the most expeditious salting of the fish. Salt uptake by the fish is partly a function of brining temperature, with salt penetration being slower at lower temperatures. Since the salt is contributory to the inhibition of Cl. botulinum outgrowth and since the brining time to attain more uniform inhibitory levels of salt can be reduced at 50°F, it is in the industry's, as well as the consumer's, best interest to brine at those conditions favoring accelerated and adequate salt uptake while not jeopardizing increased risk of bacterial proliferation (considering time, temperature, and substrate).

Pages 14 - 15 - same as NFI

DEFENDANTS' EXHIBIT B - LETTER DATED MAY 4, 1970 FROM THE ASSOCIATION OF SMOKED FISH PROCESSORS, INC. TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

When Miss Dolan phoned me Friday, May 1, 1970 to inquire when the Association's comments would be forthcoming, I advised her I was planning to contact the Bureau of Commercial Fisheries laboratory at Ann Arbor, Michigan to review the current status of their work and would appraise her of their present timetable. I have spoken with Dr. Jack Graikoski at the BCF lab (Friday 5/1/70) and he advised me that they are planning at least one more inoculated pack with the whitefish which would presumably complete their study during the early or middle part of June provided further support data is not felt to be required. Tests with sable and salmon were delayed to expedite completion of the whitefish evaluation. No timetables on completion of these studies was indicated.

As you are aware, there are a number of aspects of the proposed GMP which we did not thoroughly discuss at our meeting on April 7, 1970. I would like to reiterate our sincere desire to meet with your technical people to openly discuss these matters so that a reasonable and workable GMP for the smoked fish industry can be achieved.

I shall look forward to hearing from you.

Very truly yours,

ASSOCIATION OF SMOKED FISH PROCESSORS, IN

George W. Bierman, Ph.D.
Technical Advisor

GWB/dmb

cc: A.S.F.P. Members
Mr. Ted D. Sanford
Mr. Lee J. Weddig
Miss Mary Dolan

bl.cc: Mr. Richard Morey
Mr. Harry Seagran

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

NATIONAL FISHERIES INSTITUTE, INC.

SUITE 314
1225 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20036 (202) 659-4610

April 28, 1970

RECEIVED MAY - 4 1970

General Fred J. Delmore
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

DEFENDANT'S EXHIBIT C 6
NO. 76C647

Dear General Delmore:

This letter will confirm and amplify the comments made by various industry participants during the April 7, 1970 meeting on FDA's proposed smoked fish good manufacturing practice regulations, including the further revisions to these regulations suggested by FDA at the April 7, 1970 meeting. The industry participants are aware that the April 7, 1970 meeting did not fully resolve all the points of controversy in the proposed regulations. They believe, however, that substantial progress toward reasonable and workable regulations was achieved at the meeting. For this reason, they wish to confirm their comments made during that meeting, and to state their understanding as to various positions which, on the basis of the meeting, appear to be acceptable both to FDA and to industry.

Initially, all of the industry participants wish to express again their appreciation to you and the other FDA participants for the manner in which the April 7, 1970 meeting was conducted. The open-minded attitude displayed by FDA personnel at the meeting, in our view, will aid significantly in achieving sanitary regulations for smoked fish processing which are not only adequate to protect the public health, but are within the capability of industry.

We wish to sumit the following detailed comments on the proposed regulations. The references made are to the "Analysis of Industry Comments" which was the basis of discussion during the April 7, 1970 meeting.

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

COMMENTS

Page 2, lefthand column, second paragraph. This paragraph in the preamble to the proposed regulation suggests that some processors base their processing parameters solely on the appearance and acceptability of the finished product. This statement is, in industry's view, unjustified and factually unsupportable. It is suggested that any such statement be eliminated when the regulations are promulgated.

Page 4, lefthand column, Section 128 a.1(b). It is suggested that "loin muscle" be defined so as to exclude fat because the fat associated with the loin muscle does not contain any salt.

Page 4, lefthand column, Section 128 a.1(c). The proposed regulation provides that the percentage of salt be determined by the official AOAC method. This method is cumbersome and not suitable for regular in-plant use. It is suggested that the industry's current practice of using "quantabs" to calculate salt concentration be recognized as an alternative procedure. At the least, it should be recognized that this method is valid for in-plant use for screening purposes.

Page 5, righthand column, Section 128 a.1(e). It is suggested that the words "to cook it" at the end of this provision are redundant, and that they introduce a possible ambiguity into the meaning of the provision. NFI's original comment was that the definition should refer to products heated to 100° or higher. Since FDA pointed out that this would bring other forms of products besides the traditional hot process smoked fish within its coverage, it is now recommended that the definition simply be retained as proposed by FDA on page 5, with the exception that the words "to cook it" should be deleted.

Page 7, lefthand column, Section 128 a.3(b). The FDA proposal made mandatory separation of various processes of the fish smoking operation into separate rooms or facilities with interior walls extending from floor to ceiling. Industry generally agreed with the desirability of this requirement, but several members pointed out the extreme hardship which could be caused by its rigorous application to certain existing plants. Industry members also pointed out that while highly desirable, this requirement was not absolutely essential to prevent cross contamination between raw and finished product. Other methods, particularly careful scheduling of different processing operations at different times, also could effectively remove the hazard of cross contamination.

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

After considerable discussion, the FDA representatives at the April 7, 1970 meeting suggested that the word "shall" in this provision might be changed to "should," indicating that the requirement was not mandatory under all circumstances. Industry strongly supports this change in language which would spell out a requirement for use in all applicable situations without causing extreme hardship to industry members whose plants cannot be adapted to meet the requirement.

Page 9, lefthand column, Section 128 a.6(b). As proposed, this provision would prevent any "nesting" of containers used to convey or store fish at any time. Industry members pointed out that these containers are commonly stored by "nesting" when not in use, and that failure to allow this would create serious space problems. Industry personnel also pointed out that there was a difference between "nesting" and "stacking" where the containers rest on top of each other but no portion of one container is inside another container as in "nesting."

FDA personnel indicated no objection to "stacking," or to "nesting" during storage. Accordingly, it is recommended that this provision be revided to read:

> "(b) Containers used to convey or store the fish shall not be nested (during processing) (while they contain fish) or otherwise handled in a manner conducive to direct or indirect contamination of their contents."

Page 9, righthand column, Section 128 a.7(a) (1). Industry representatives object to this provision as presently worded on several grounds. First, it might be taken to mean that the fish must be washed immediately upon receipt rather than merely before processing. Second, the provision implies that processors regularly receive filthy, putrid or decomposed fish, which is not the case. Finally, the references to "bruised" and "otherwise adversely damaged" might be applied to prevent processing of fish which have merely aesthetic defects but are entirely wholesome. Accordingly, as discussed during the April 7, 1970 meeting, it is suggested that this provision be amended to read as follows:

> "(1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish, free from adulteration and organoleptically detectable spoilage shall be processed."

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

Page 10, lefthand column, Section 128 a.7(a) (3). As proposed, this would require that all fresh or partially frozen fish be received by the processor at an internal temperature of 38° or below. Industry members pointed out that all such fish received simply will not be at that low a temperature, especially during the summer. It also was pointed out that the important factor was that the processor chilled the fish after receipt, not the temperature at which they were received. This is because Type E C. botulinum produce toxin very slowly at less than 50°F. It was estimated that at such temperatures, it would be two weeks before botulinum presented any hazard, and that putrification would have occurred well before that time.

It was agreed at the meeting that industry members would collect data on the temperature at which such fish were received and advise FDA on the basis of this data. Accordingly, industry recommends that consideration of this provision be postponed until such data has been collected and reviewed.

Page 10, lefthand column, Section 128 a.7(a) (4). As proposed, this provision would require all frozen fish to be received and stored at 0°F. or below. Industry members pointed out that there was no justification for a requirement of 0° or any other particular temperature so long as a frozen state was maintained. FDA representatives thereupon indicated their agreement with the language previously proposed in the National Fisheries Institute comments. Accordingly, the industry participants again recommend that the provision be changed to read as previously recommended by the National Fisheries Institute, as follows:

> "(4) All fish received in a frozen state shall be either thawed promptly and processed or stored at a temperature that will maintain it in a frozen state."

Page 11, lefthand column, Section 128 a.7(b) (2). At the April 7, 1970 meeting, industry and FDA representatives agreed that the word "thawed" should be changed to "completely defrosted" in this provision to remove the ambiguity introduced by the use of the word "thawed."

Page 12, righthand column, Section 128 a.7(b) (4). As proposed by FDA, this provision would require that the fish be washed after removal from the thaw tank. Industry representatives pointed out that current practice is to wash the fish in the thaw tank since washing and thawing can be accomplished simultaneously using the continuous flow system. It was therefore agreed at the meeting that the words "on removal from the thaw tank" should be deleted from this provision. The industry participants continue to recommend that this change be made.

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

Page 13, righthand column, Section 128 a.7(c) (3). As proposed, this provision would require that all fish be brined in a solution that does not exceed 38°F. Industry representatives pointed out that this would present serious problems because city water customarily is used to make the brining solutions, and the brine temperature is governed by the temperature of the water used. During substantial portions of the year, it would not be possible to meet the 38° requirement.

Industry representatives therefore recommended that a 50° maximum temperature requirement be imposed instead. It was pointed out that below this temperature there is no serious danger from Type E C. botulinum.

At the April 7, 1970 meeting, FDA representatives stated that this issue would have to be submitted to FDA microbiologists for comments. The industry participants continue to recommend a 50° maximum temperature for the brining solution and will be prepared to discuss this matter in detail with the FDA microbiologists.

Pages 14-15. These pages contain the processing requirements which are the major point of controversy between FDA and industry as to these regulations on smoked fish. As the regulations were initially proposed, there was a general processing requirement of 180°F., 30 minutes and 3.5 percent salt content. During the April 7, 1970 meeting, FDA representatives also offered an additional set of processing parameters of 150° F., 30 minutes and 5 percent salt content which was in agreement with the National Fisheries Institute's earlier comment on the FDA proposal.

Industry participants at the April 7, 1970 meeting, however, pointed out that recent experimental work showed difficulties in meeting either of the sets of processing parameters suggested by FDA as to a number of species of fish. The industry representatives at that time submitted for FDA's consideration several reports describing attempts to achieve the original processing conditions proposed by FDA, as well as a general study on the methods of heating smoked fish. It was also noted that further studies, involving other species of fish, presently were being run by the Bureau of Commercial Fisheries. It was agreed that these studies also would be submitted to FDA upon completion.

In addition, industry representatives raised questions about the methods of temperature recording required under the proposed regulations, pointing out the sizable variation in smokehouse temperature even with the most sophisticated equipment and the difficulties of securing accurate and representative temperature readings.

DEFENDANTS' EXHIBIT C - LETTER DATED APRIL 28, 1970 FROM NATIONAL FISHERIES INSTITUTE TO GENERAL FRED J. DELMORE, FOOD AND DRUG ADMINISTRATION

It was agreed at the April 7, 1970 meeting that all of these points would have to be discussed further between industry representatives and the FDA microbiologists. The data submitted by industry at the meeting would be studied by FDA and a meeting would be held as agreed between industry representatives and FDA.

The industry representatives are hopeful that these comments will serve to confirm the agreements reached at the meeting of April 7, 1970 and also to provide a basis for the proposed meeting with the FDA microbiologists to consider the points which were left unresolved at that meeting. Finally, the industry representatives wish to emphasize again their desire to cooperate with FDA to achieve sound and workable regulations governing the processing of smoked fish.

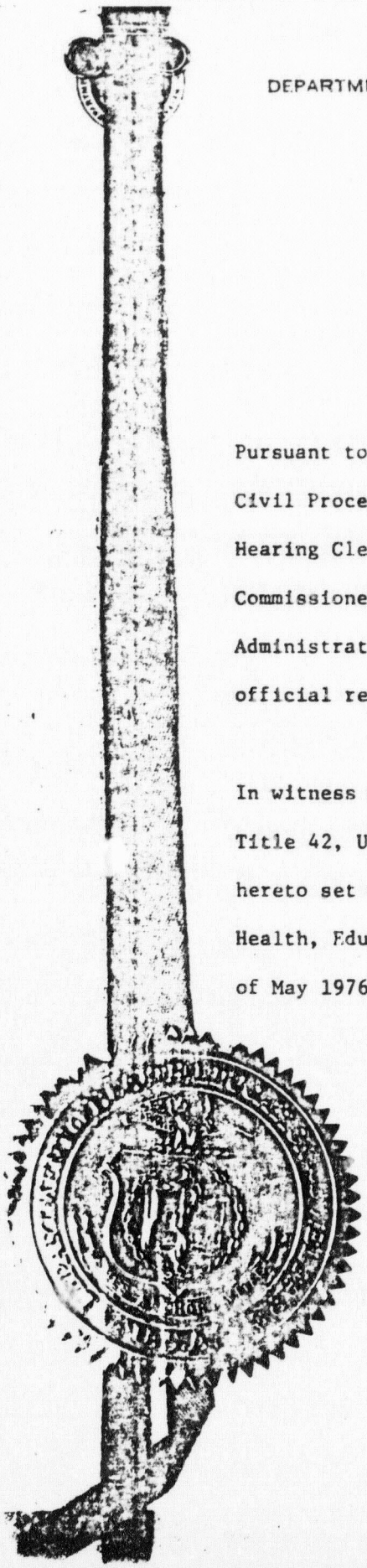
Respectfully submitted,

NATIONAL FISHERIES INSTITUTE

Ted D. Sanford
Director Technology

Lee J. Weddig
Executive Director

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Jennie C. Peterson, Hearing Clerk, Public Records and Documents Center, Associate Commissioner for Compliance, United States Food and Drug Administration, whose affidavit is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, Section 3505, and 21 CFR 2.121(d), hereto set my hand and caused the seal of the Department of Health, Education, and Welfare to be affixed this 10th day of May 1976.

Edward J. Costello,
Edward J. Costello, Supervisor
Public Records and Documents Center
Associate Commissioner for Compliance

By direction of the Secretary of
Health, Education, and Welfare

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

AFFIDAVIT

Jennie C. Peterson, Being first duly sworn, deposes, and says:

1. I am Hearing Clerk, Public Records and Documents Center, Associate Commissioner for Compliance, United States Food and Drug Administration.

2. In this capacity I have custody of official records of the United States Food and Drug Administration.

3. Attached is the file entitled "#128a GMP (Sanitation) Smoked Fish" promulgated by the proposal published in the Federal Register on October 23, 1969 (34 FR 17176), and finalized by the order published in the Federal Register on November 13, 1970 (35 FR 17401.)

4. Copies of this file are part of the official records of the United States Food and Drug Administration.

Jennie C. Peterson

County of Montgomery
State of Maryland

Subscribed and sworn to before me this 10th day of May 1976.

Notary Public
MARY B. GARRETT

My Commission Expires July 1 1979

A-633

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

TWining 4-1400

REGO SMOKED FISH CO., INC.

69-80 75th Street • Middle Village, N. Y. 11379

DECEMBER 7th, 1970

Hearing Clerk
Department of Health, Education, and Welfare
Room 6-62
5600 Fishers Lane, Rockville, Maryland, 20852

Dear Sir;

The writer was present at a meeting held on April 7th, 1970, at which, General Delmore had agreed to a technical meeting with Industry to discuss processing conditions prior to final publication of the GMP for Smoked Fish. Since this meeting was never held, we object to the publication of the GMP,s for Smoked Fish as published in the FEDERAL REGISTER dated, Friday, November 13th, 1970, and we respectfully request a STAY until such a meeting is held.

We object to the added coverage of "SMOKE-FLAVORED FISH", because this is an imitation product, and, in accordance with other FDA Regulations for other such "IMITATION" foods, should be required to be labeled, "IMITATION". The New York City Smoked Fish Industry has always produced and wishes to continue to produce a GENUINE product and would object to the lowering of the quality of the products sold in this area. We believe that this new suddenly included "PRODUCT" could be produced out of our area and could compete to the detriment of our industry.

We reiterate our previous claim that the processing requirements cannot be applied to all species of fish, and, we again, respectfully, request that FDA be required to specify Time and Temperature requirements, as developed by THEIR research and study on a species by species basis.

We again submit that before final establishment of processing requirements, adequate studies should be concluded.

128a.7(e): The modified requirement allowing to cool to 50°F within 3 hours and to 38°F or below within 12 hours could be achieved by the processor. However, the requirement to maintain 38°F during all subsequent storing and distribution is unrealistic.

128a.7(e)sub.par.5; The coding requirements are of limited value since the jobbers and retailers buy from more than one source and make up their orders by mixing various fish from different plants.

Even though, at industry urging, the mandatory requirement to seperate, by floor to ceiling partition, was changed from "SHALL" to "SHOULD" for processes involving (1) receiving and shipping; (2) storage of raw fish; (3) pre-smoking operations, (thawing, dressing, brining, etc.) and, (4) drying and smoking, the mandatory requirements to partition rooms or facilities for processing involving (1) cooling and packing; (2) storage of final product, again is unrealistic and presents an impossible burden upon some existing processing plants. The regulation for new plants is excellent but a "GRANDFATHER" clause to permit existing plants to continue to operate is vitally necessary.

Respectfully submitted, December 7th, 1970.

Conrad Spizz

Conrad Spizz 12-7-70

BEST COPY AVAILABLE

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BERYL MORRISON, HEARING CLERK (GC 1)
[illegible] BLDG.
[illegible]
ROCKVILLE, MARYLAND 20852

DUPLICATE ORIGINAL

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

35 FR 17401 Nov 13, 1970

SUBCHAPTER B--FOOD AND FOOD PRODUCTS

PART 128a--FISH AND SEAFOOD PRODUCTS

Part Nov 13 Fri

SUBPART A--SMOKED AND SMOKE-FLAVORED FISH

CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING OF SMOKED AND SMOKE-FLAVORED FISH FOR HUMAN FOOD

In the FEDERAL REGISTER of October 23, 1969 (34 F.R. 17176), the Commissioner of Food and Drugs proposed regulations (Subpart A, Part 128a) covering current good manufacturing practice (sanitation) in the manufacture, processing, packing, or holding of smoked fish. In response, comments were received from two trade associations, eight manufacturers, and the Bureau of Commercial Fisheries, Department of Interior. The comments include opposition to certain requirements and suggestions for clarifying and technical changes.

The principal objection is that the process requirements in the proposed regulations cannot be applied to all species of fish presently being smoked by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis.

The Commissioner finds: (1) That although adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements for fish presently

requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of C. botulinum Type E; and (2) that since the public health hazard of C. botulinum Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay.

Therefore, having considered the comments received and other relevant material, the Commissioner concludes that the proposed regulations, with most of the suggested clarifying and technical changes incorporated, should be adopted as set forth below. Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), the following new Subpart A is added to Part 128a:

SUBPART A--SMOKED AND SMOKE-FLAVORED FISH

Sec.

128a.1 Definitions;

128a.2 Current good manufacturing practice (sanitation).

128a.3 Plants and grounds.

128a.4 Equipment and utensils.

128a.5 Sanitary facilities and controls.

128a.6 Sanitary operations.

128a.7 Processes and controls.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

- 3 -

§ 128a.1 Definitions.

(a) Smoked fish. As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.

(b) Smoke-flavored fish. As used in this part, the term "smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke. This paragraph does not alter the labeling requirements under § 3.201 of this chapter.

(c) Loin muscle. As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(d) Water phase salt. As used in this part, "water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th edition, page 273 (1965), multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of said edition.

(e) Hot-process smoked or hot-process smoke-flavored fish. As used in this part "hot-process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraphs (a) and (b) of this section to heat as prescribed in § 128a.7(d).

§ 128a.2 Current good manufacturing practice (sanitation).

(a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this Subpart A set forth additional requirements for the hot-process smoked or hot-process smoke-flavored fish industry.

§ 128a.3 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes should be carried out in separate

rooms or facilities, and the interior walls separating these processes should extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Receiving or shipping.

(2) Storage of raw fish.

(3) Presmoking operations (thawing, dressing, brining, etc.).

(4) Drying and smoking.

(c) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Cooling and packing.

(2) Storage of final product.

(d) The product shall be so processed as to prevent contamination by exposure to areas, utensils, or equipment involved in earlier processing steps, refuse, or other objectionable areas.

§ 128a.4 Equipment and utensils.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature-measuring devices shall have an accuracy of $\pm 2^{\circ}$ F.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents.

(c) Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

§ 128a.7 Processes and controls.

(a) Raw materials. (1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated to an internal temperature of 38° F. or below upon receipt and shall be maintained at that temperature until the fish are to be processed.

(4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.

(b) Defrosting of frozen fish. (1) Defrosting shall be carried

out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:

(i) In air at 45° F. or below until other than hard frozen; or

(ii) In air so that the temperature in any part of the fish does not exceed 45° F.; or

(iii) In a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are completely defrosted.

(3) Fish entering the thaw tanks shall be free of exterior packaging material and substantially free of liner material.

(4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.

(c) Presmoking operation. (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous water spray or a continuous waterflow system.

(3) All fish shall be brined in a solution that does not exceed 38° F. or dry-salted at a temperature not to exceed 38° F. throughout the fish.

(4) Hot-process smoked or hot-process smoke-flavored fish shall

be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d)(2)(i) of this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d)(2)(ii) of this section.

(5) Fish shall be rinsed with fresh water after brining.

(d) Heating, cooking, smoking operation. (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

(i) Not less than 180° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c)(4)(i) of this section, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.0 percent water phase salt in the finished product as prescribed in paragraph (c)(4)(ii) of this section.

(e) Packing. (1) The finished product shall be handled only with clean, sanitized hands, gloves, or utensils.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to a temperature of 50° F. or below within 3 hours after cooking and further cooled to a temperature of 38° F. or below within 12 hours after cooking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F. or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify at least the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification (i) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish and (ii) of the distribution of the finished product.

(f) Testing. (1) Microbiological examination of in-line and

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

finished product samples should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

(2) The finished product shall be analyzed chemically with sufficient frequency to assure that the required salinity is obtained in every fish and that other chemical additives are present at authorized levels.

Effective date. This order shall become effective 30 days after its date of publication in FEDERAL REGISTER.

(Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a))

Dated: NOV 2 1970.

Sam D. Fine
Associate Commissioner for
Compliance.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

J. E. Davis

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

SUMMERLIN'S

BAYWOOD FISHERY

724 SEAWAY DRIVE

FORT PIERCE, FLORIDA 33450

Dec.1,1969

Hearing Clerk
Dept.Health Ed. and Welfare
Room 5440
330 Independence Ave. S.W.
Washington D.C. 20201

Dear Sir.

In regards to the notice in the Federal Register, Nov. 22,1969on fish and seafood products. G.M.P.'s for smoked fish. Under section 128A-7-d4 smoked fish shall be labeled to specify the product shall be shipped, stored and held for sale at 38 F. or below.

We have operated A smoked fish mail order business here for the past 24 years. We ship our product by parcel post all over the United States. In this time We have shipped approxmately 100,000 lbs. of our smoked products.

Will this new G.M.P. pervent us from shipping smoked fish in the mail ? If so is there some other course we can take to stay in the mail order business.

Very Truly Yours
B. A. Summerlin

B A Summerlin

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

TWining 4-1400

REGO SMOKED FISH CO., INC.

69-80 75th Street • Middle Village, N. Y. 11379

November 19th, 1969

Hearing Clerk
Department of Health, Education and Welfare
Room 5440
330 Independence Avenue, S. W.
Washington, D. C., 20201

Re: Proposed Current Good Manufacturing Practice, (Sanitation) Section 128a.3.

Dear Sirs:

As a producer who has been in the Smoked Fish Business at this same location since September, 1949,-and as one who has participated and cooperated with the F.D.A,, The New York State Department of Agriculture and Markets, and the New York City Department of Health in the development of the proposed "Good Manufacturing Practices",-I cannot understand the attempt to promulgate the proposed standards, as published in the Federal Register of October 27th, 1969, without the inclusion of the standard "Grandfather Clause", usually included in all such type regulations.

At the various joint committee meetings of our Industry and the aforementioned agencies it was universally agreed and accepted by All participants that such a "Grandfather Clause" to protect the existing processing plants was necessary. Even those representatives of the F.D.A. agreed to this need.

To have published these Good Manufacturing Practices without such a clause is not only unconscionable, but is a violation of the AMERICAN DEMOCRATIC CONCEPT and would put all existing smoked fish plants in the United States in jeopardy of being forced out of business, should Section 128a.3, referring to plants and grounds, be strictly enforced as written.

We have applied for a loan from the Small Business Administration. We were turned down. Be that as it may, we could not comply with the proposed regulations except by tearing down our entire plant and starting from scratch.

Fully cognizant of our responsibilitées to produce a clean and wholesome product under G.M.P. and Sanitary Procedures,-we respectfully suggest and request that a "Grandfather Clause"be included exempting all existing plants from meeting the physical plant specifdcations of the section.

In addition, we understand that the Association of Smoked Fish Processors, Inc.., through their technical experts, are submitting additional objections-to which, we also subscribe.

We respectfully request that our personal objection and the objections of our Association receive all due consideration and review.

Respectfully yours,

Conrad Spizz, Secty.-Treas.

14

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

TWining 4-1400

REGO SMOKED FISH CO., INC.

69-80 75th Street • Middle Village, N. Y. 11379

NOVEMBER 21st, 1969

Hearing Clerk
Department of Health, Education and Welfare
Room 5440
330 Independence Avenue, S.W.
Washington, D.C., 20201

Dear Sirs;

Re; Good Manufacturing Practice, (Sanitation)
Section 128a.3

Reference is made to our letter dated November 19th, 1969.

We refer specifically to the first paragraph, wherin we stated that the Proposed Regulations for Good Manufacturing Practices was published in the Federal Register of October 27th, 1969.

This is an error.

The date of the publication in the Federal Register of the aforementioned PROPOSED Regulations was OCTOBER 23rd, 1969— VOLUME 34 #204.

We respectfully request your attention to this correction.

Respectfully yours

Conrad Spizz, Secty.-Treas.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Association of Smoked Fish Processors, Inc.

TECHNICAL CENTER

54 CLAYTON STREET
BOSTON, MASSACHUSETTS 02122

AREA CODE 617
825-1812

Certified Mail
Return Receipt Requested

November 18, 1969

Hearing Clerk
Department of Health, Education & Welfare
Room 5440
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Proposed Current Good Manufacturing Practice (Sanitation) 21 CFR Part 128a - Fish and Seafood Products Subpart A - Smoked Fish

Dear Sir:

Reference is made to the proposed regulations setting forth specific manufacturing practice (sanitation) requirements regarding hot processed smoked fish (21 CFR Part 128a Subpart A - Human Foods; Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing or Holding - Smoked Fish) published in The Federal Register, Volume 34, No. 204, Thursday, October 23, 1969 pages 17176 through 17178.

The Association of Smoked Fish Processors, Inc., which represents the major smoked fish processing industry in the New York area wishes to file the following written comments regarding the above referenced proposal.

Since 1963, the processors of smoked fish have made significant changes in their facilities, equipment, utensils, processing practices and controls to improve the sanitation of their manufacturing operations in order to minimize the hazard of Type E botulism and the risks of food-borne infections due to the consumption of smoked fish. The effectiveness of this effort has been demonstrated by the absence of any botulism outbreaks since that time due to smoked fish, and to the minimum incidence of other food-borne infections related to this group of food products.

Members of the Association take exception to the image of irresponsibility cast upon the smoked fish industry by the statement in the preamble to the proposed regulations by the Food and Drug Administration that "currently, the situation exists whereby some processors base their manufacturing practices solely on the appearance and acceptability of the finished product quality to consumers rather than on any specific or controlled processing parameters that would minimize the health hazard of C. botulinum Type E or its toxins." Smoked fish processors are keenly aware of the potential public health hazards

Re: Proposed Current Good Manufacturing Practice (Sanitation)
21 CFR Part 128a - Fish and Seafood Products
Subpart A - Smoked Fish

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associated with inadequate processing and abusive handling of their products and, consequently, have taken positive constructive action to improve their facilities, sanitation and manufacturing practices. The implication that they have done otherwise is unjust.

The Association is aware of the need for, and is receptive to, promulgation of a uniform code of sanitary standards that can be used as a basis of equitable regulatory enforcement throughout the industry. The Association is also aware, however, that while uniform requirements of sanitation and sanitary operation can be expected, uniformity in processing procedure among different species of fish is commercially unrealistic.

The proposed process requirements suggested by the FDA for hot processed smoked fish are neither commercially feasible nor based on sound scientific evidence obtained with the variety of smoked fish products to be included under this regulation. It has been repeatedly demonstrated that consumer acceptable smoked chubs cannot be prepared when processing conditions require that the coldest portion of the slowest heating fish in a smokehouse must attain a temperature of 180°F for 30 minutes. Other varieties of fish are even more heat sensitive. Processing conditions which minimize the necessity for high temperature treatment must be adopted if the consumer is to continue to enjoy the products she has become accustomed to. Work now underway by the Bureau of Commercial Fisheries on several varieties of fish have indicated very encouraging preliminary results with lower temperature processing in combination with specific salt and nitrite levels.

The Association strongly feels that the GMP regulations for smoked fish be inclusive of good manufacturing practices that pertain to environmental aspects of the plant and process, but exclude references to processing techniques that may vary significantly with the various fish products. Specification of processing parameters should be published as amendments to the Smoked Fish GMP as they are scientifically established through the coordinated effort of industry, the Bureau of Commercial Fisheries and the Food and Drug Administration.

In addition to the above objections, we would also like to comment specifically regarding particular wording in the body of the regulations which we feel is ambiguous, difficult to interpret, or incompleted, and requirements which are not practical commercially or technically justified.

Para. 128a.1(a) Change to:

> Smoked Fish. As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and which, for the prime purpose of taking

Hearing Clerk -3- November 18, 1969
Dept. Health, Education & Welfare

Re: Proposed Current Good Manufacturing Practice (Sanitation)
21 CFR Part 128a - Fish and Seafood Products
Subpart A - Smoked Fish

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on the flavor and/or color of smoke, has been (1) subjected to the direct action of smoke or smoke flavor from the burning of wood, wood sawdust, or similar burning material; or (2) immersed in or sprayed with a smoke-flavored solution.

Para. 128a.1(c) Add:

Other methods of comparable accuracy may be used.

Para. 128a.1(d) Revise as follows:

Hot process smoked fish. As used in this part, "hot process smoked fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraph (a) of this section to a drying and heating operation. The food additive sodium nitrite may be used in accordance with the conditions prescribed by paragraphs 121.1064 and 121.1230 of this chapter.

Para. 128a.3(b) Revise as follows:

The following processes shall be carried out in separate rooms, areas or facilities so arranged to prevent contamination from product in earlier stages of processing:

(1) Receiving
(2) Storage of raw fish
(3) Presmoking operations (thawing, dressing, brining, etc.)
(4) Drying and smoking
(5) Cooling and packing
(6) Storage of finished product
(7) Shipping

Para. 128a.3(c) Revise as follows:

The processing of product shall be so scheduled as to prevent contamination by exposure to areas, equipment or utensils involved in earlier processing steps, refuse or other objectionable areas.

Para. 128a.6(b) Revise as follows:

Containers used to convey or store smoked fish or fish products in process shall not be handled in a manner conducive to direct or indirect contamination of contents.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Re: Proposed Current Good Manufacturing Practice (Sanitation
21 CFR Part 128a - Fish and Seafood Products
Subpart A - Smoked Fish

Para. 128a.6(c) Revise as follows:

Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

Para. 128a.7(a)(1) Revise as follows:

Raw materials. (1) All fish received shall be inspected and only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

Para. 128a.7(a)(3) Revise as follows:

Upon receipt, fresh or partially processed fish, except those to be immediately processed, shall be chilled with ice or refrigerated to an internal temperature of 40°F or below and shall be maintained at that temperature until the fish are to be processed.

Para. 128a.7(b)(1)(i) Revise as follows:

In air so that the temperature of the fish does not exceed 45°F; or

Para. 128a.7(b)(1)(ii) Revise as follows:

In a thaw tank or spray system using potable municipal water.

Para. 128a.7(b)(3) Revise as follows:

Fish entering the thaw tanks shall be free of packaging material except portions of inner wrap material.

Para. 128a.7(b)(4) Revise as follows:

After fish is thawed it should be washed thoroughly with either a spray or continuous water flow before being brined.

Para. 128a.7(c)(2) Revise as follows:

After the evisceration process, the fish shall be thoroughly washed by means of a continuous spray system or a continuous water flow.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Hearing Clerk -5- November 18, 1969
Dept. Health, Education & Welfare

Re: Proposed Current Good Manufacturing Practice (Sanitation)
21 CFR Part 128a - Fish and Seafood Products
Subpart A - Smoked Fish

Para. 128a.7(c)(3) Revise as follows:

All fish shall be brined in a solution that does not exceed 50°F.

Para. 128a.7(c)(4) Delete and include salt requirement with process parameter for specific species as established.

Para. 128a.7(d)(1) Delete

Para. 128a.7(d)(2) Delete and include temperature and time requirement with process parameter for specific species as established.

Para. 128a.7(e)(3) Revise as follows:

The finished product shall be cooled to a temperature of 38°F within 12 hours after smoking and this temperature shall be maintained during all subsequent storage by the processor.

Para. 128a.7(f)(1) Revise as follows:

The finished product shall be examined microbiologically with sufficient frequency to assure that processing steps and sanitation of procedures are adequate.

The above revisions in the proposed Good Manufacturing Practice (Sanitation) for hot processed smoked fish are considered to be both reasonable and practical from a technical and commercial standpoint without jeopardizing consumer protection.

Based on the Good Manufacturing Practice (Sanitation) for hot processed smoked fish proposed by the Food and Drug Administration, there is an evident need for closer liaison and constructive cooperation between Government and Industry in the preliminary drafting of workable regulations in this industry.

We shall look forward to the opportunity of discussing the proposed regulations with you in greater detail.

Respectfully submitted,
ASSOCIATION OF SMOKED FISH PROCESSORS, IN

George W. Bierman

George W. Bierman, Ph.D.
Technical Advisor

GWB/dmb

cc: See Attachment

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Hearing Clerk -Attachment- November 18, 1969
Dept. Health, Education & Welfare

Re: Proposed Current Good Manufacturing Practice (Sanitation)
21 CFR Part 128a - Fish and Seafood Products
Subpart A - Smoked Fish

Copies of foregoing to all members, Association of Smoked Fish Processors, Inc., as follows:

Acme Smoked Fish Corp.
Horowitz Bros. Smoked Fish Products Co.
Vita Food Products, Inc. (Schnibbe Division)
Marshall Smoked Fish Co.
Montrose Smoked Fish Co.
Nova Scotia Food Products Corp.
Rego Smoked Fish Co.
Vita Food Products, Inc.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

PACKERS, CURERS AND SMOKERS OF ALL KINDS OF FRESH AND SALT WATER FISH.

NOVA SCOTIA

FOOD PRODUCTS CORPORATION

212 388-2876

77 LOMBARDY STREET, BROOKLYN, NEW YORK 11222

November 21, 1969

Hearing Clerk
Department of Health, Education & Welfare
Room 5440
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Sir:

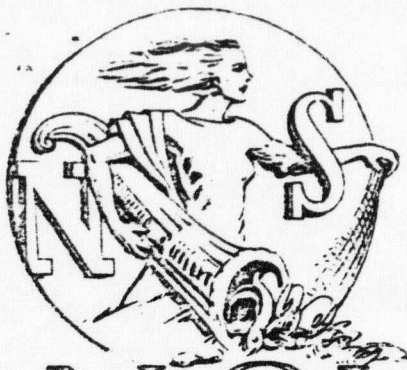
Reference is made to the proposed regulations setting forth specific manufacturing practice (sanitation) requirements regarding hot processed smoked fish (21 CFR Part 128a Subpart A- Human foods; Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing or holding-Smoked Fish) published in The Federal Register, Volume 34, No. 204, Thursday, October 23, 1969 pages 17176 through 17178.

We concur with the objections and exceptions contained in the written communication, sent separately, by the Association of Smoked Fish Processors, Inc. (Techinical Center). Most of the objections deal with technical and other practical matters the reasons for which could best be handled at a hearing rather than in interminable written material.

We beleive, however, that it is important now to provide you with some general philosophy of reasoning that affects the whole body of the proposed regulations as it specifically applies to smoked fish.

Continued, please see page-2-

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD



PACKERS, CURERS AND SMOKERS OF ALL KINDS OF FRESH AND SALT WATER FISH.

NOVA SCOTIA

FOOD PRODUCTS CORPORATION

212 388-2873

77 LOMBARDY STREET, BROOKLYN, NEW YORK 11222

(-Continued, page 2-)

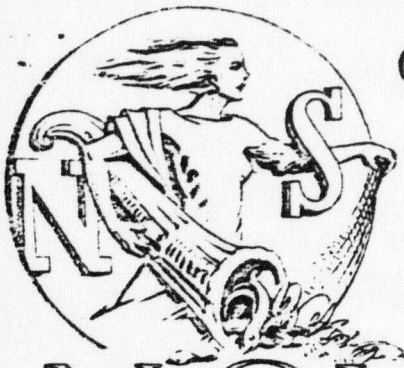
1- Certain proposed requirements are impossible or impractical. For example, (a) the heating of certain types of fish to high temperatures will completely destroy the product!; (b) very cold brinning temperatures will not premit the absorption of salt by the fish. These are only examples and apply to other parts of the proposed regulation.

2- Inasmuch as the Food and Drug Administration acknowledges in the third paragraph of the Preamble (page 17176) "that adequate times, temperatures, and salt concentrations have not been demostrated for each individual species of fish presently smoked," it follows that blanket processing procedures other than sanitary considerations are improper, unfair, and will lead to undue hardship for individuals and the public. As an alternative to this section of the proposed regulation, part 128a.7 and in particular to paragraph (d) (1) and (2), specific processing procedures could be established for each species after adequate work and experimention has been done-but not before.

3- Certain proposals will require major alterations of exisiting Plants or the building of new plants. Such construction takes time. Take, for example, a fish smoking plant which is so constructed that it has only one opening for shipping and receiving and this condition cannot be changed for physical reasons. This plant cannot comply with Section 128a.3 (Plants and Grounds). In this case reasonable time should be given to allow for moving to another facility or building a new plant. In those plants where it is physically possible to make structural changes time should be allowed for that too.

Continued, please see page-3-

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD



PACKERS, CURERS AND SMOKERS OF ALL KINDS OF FRESH AND SALT WATER FISH.

NOVA SCOTIA FOOD PRODUCTS CORPORATION

212 388-2876

77 LOMBARDY STREET, BROOKLYN, NEW YORK 11222

-CONTINUED-PAGE-3-)

Nothing in this letter should be construed as an unwilligness to cooperate with the Food and Drug Administration. Our point is, that the new regulation should not contain impossible requirements or impractical rules, nor cause undue hardship on the industry, it's employees or the public. Furthermore, where large scale monetory investments and/or major construction will become necessary, sufficient time should be granted to accomplish these objectives.

Respectfully Submitted,
NOVA SCOTIA FOOD PRODUCTS CORP.

DAVID SKLAR
VICE-PRESIDENT

DS:pd

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

November 20, 1969

Commissioner of Food and Drugs
Department of Health, Education and Welfare
Washington, D. C. 20204
Attention: Hearing Clerk

Dear Sir:

Development Consultants, Inc., a Corporation organized under the laws of the State of Ohio and having a principal place of business at 5657 Vine Street, Cincinnati, Ohio 45216 by and through its attorney respectfully petitions the Commissioner for modification of the proposed Rule 21 CFR Part 128a HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING Smoked Fish.

Petitioner is the owner of ZESTISMOKE process for imparting smoky flavoring to comestibles in general which process has particular utility for imparting smoky flavoring to meat and fish. In general the process comprises utilizing liquid smoke by nebulizing the liquid smoke to form a cloud of the liquid smoke and exposing the comestible product to the cloud of liquid smoke while the comestible is maintained at room temperature, or heated depending upon whether the product is to be hot or cold processed. The liquid smoke consists of a clear aqueous solution prepared by condensing or precipitating wood smoke in water.

The proposed Rule, 21 CFR Part 128a as reported in the Federal Register, Vol. 34, No. 204 on October 23, 1969, if adapted would cause Petitioner irreparable harm by precluding the carrying out of its useful and proprietary process in the hot processing of fish.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Specifically the proposed Rule §128a.1(a) defines smoked fish as --"any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the action of smoke from burning wood, sawdust, or similar material" [emphasis added].

It is submitted that Subpart (a) should be amended by including at the end thereof or having added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water so that the subparagraph would read as follows:

"Smoked fish. As used in this part, the term 'smoked fish' means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the action of smoke from burning wood, sawdust, or similar material or having added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water."

Granting of this petition would also require revision of §128a.7(d)(1) and (2) by cancelling the term "smokehouse" and substituting smoke-imparting chamber.

The terminology employed in amending §128a.1(a) is terminology which has been approved by this Agency and the Commissioner's attention is respectfully directed to Federal Register, Vol. 34, No. 192, October 27, 1969, page 15555 §19.510(d)(1). The Commissioner will also respectfully note that Development Consultants, Inc., the Petitioner herein, was the joint Petitioner with County Line Cheese Co. in respect to the amendment of Title 21 Chapter 1 Subchapter B Part 19 of the Act.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Petitioner notes that the primary function of the new Rule was to minimize the "hazard of Type E botulism and the risks of food-borne infections..." Thus the important limits of the Rule are the paragraphs relating to sanitation, the addition of salt to the product and the application of high temperature for a predetermined time to the fish product. It is submitted that the means for imparting a smoky flavoring to the product is of substantially no consequence in the control of Type E botulism. It is therefore submitted that the proposed Rule may be amended as proposed herein without departure from the sanitation and health standards of the Rule.

Petitioner requests an oral hearing.

Respectfully submitted,

DEVELOPMENT CONSULTANTS, INC.
By Its Attorney

Harold L. Stowell

739 Warner Building
Washington, D. C. 20004
Tel: 628-3233

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

ADDRESS ONLY THE DIRECTOR,
BUREAU OF COMMERCIAL FISHERIES

UNITED STATES
DEPARTMENT OF THE INTERIOR
FISH AND WILDLIFE SERVICE
BUREAU OF COMMERCIAL FISHERIES
WASHINGTON, D.C. 20240

November 21, 1969

Mr. J. K. Kirk
Associate Commissioner for Compliance
Food and Drug Administration
Department of Health, Education,
and Welfare
Washington, D. C. 20204

Dear Mr. Kirk:

We have carefully reviewed the proposed good manufacturing practices for manufacturing, processing, packing, or holding smoked fish as published in the Federal Register of October 23, 1969. As you know, this Bureau has been carrying out research for several years to develop hygienic and processing procedures that will enable production of wholesome and high quality smoked fish products. We believe there is a need for regulations setting forth specific manufacturing practices for hot processed smoked fish that would serve two objectives: (1) provide the consuming public with wholesome products; and (2) allow the processing industry practical means to produce such products which would in turn be marketable.

The proposed GMP for hot processed smoked fish sets forth sanitation standards that will minimize hygienic hazards and will improve the quality of smoked fish. For the reasons stated in my letter to you of September 26, 1969, unfortunately, the processing requirements presently proposed, which provide no alternate procedures, preclude attainment of the second objective by industry for the majority of hot processed smoked fish products presently being manufactured. Experimental data available to us indicates that it may be possible to meet both of the above objectives on a practical basis by selecting processing criteria for each species that would ensure wholesomeness with minimum changes in the acceptability of the hot smoked fish product.

In our petition for nitrite, we showed that wholesomeness considerations could be more practically and adequately realized by reducing processing temperature and using suitable concentrations of nitrite and salt. Our work also suggests, for example, that if the minimum level of salt (sodium chloride) in the water phase of hot smoked fish is increased, this would allow for a significant reduction in the processing temperature required which in turn would maintain assurance of consumer safety without elimination of the marketability of most hot smoked fish products. In addition, the use of higher salt levels would lessen the dependency

on temperature as a means to inhibit Clostridium botulinum Type E outgrowth, inasmuch as residual salt content can be readily monitored post processing.

As mentioned above, such an alternative of higher salt concentrations could be used as an interim measure until such time as on-going and future research to define processing parameters for other species are completed. We would be pleased to make specific suggestions to you that will provide on an interim basis a more practical alternative for the various species than the processing conditions specified in the good manufacturing practices.

Another alternative would be, at this time, to limit your description of good manufacturing practices to that which pertain only to plant sanitation aspects. An additional section with appropriate subsections could provide for specific processing requirements on an individual species basis as they are developed. In this regard, we are enclosing a conceptual format using smoked chub as an example.

Thank you for providing us this opportunity to comment before the GMP is published as rulemaking.

Sincerely yours,

Joseph W. Slavin
Assistant Director for
Utilization and Engineering

Enclosure

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE
Food and Drug Administration
(21 CFR Part 128a)

HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING

Smoked Fish

(----)

PART 128a-FISH AND SEAFOOD PRODUCTS

Subpart A-Smoked Fish--General

Sec.

128a.1 Definitions.
128a.2 Current good manufacturing practice (sanitation).
128a.3 Plants and gounds.
128a.4 Equipment and utensiles.
128a.5 Sanitary facilities and controls.
128a.6 Sanitary operations.
128a.7 Process and controls.

AUTHORITY: (----)

128a.1 DEFINITIONS.

(a) Smoked fish
(b) Loin muscle
(c) Water phase salt
(d) Hot process smoked fish

128a.2 CURRENT GOOD MANUFACTURING PRACTICE (SANITATION).

128a.3 PLANTS AND GROUNDS.

128a.4 EQUIPMENT AND UTENSILES.

128a.5 SANITARY FACILITIES AND CONTROLS.

128a.6 SANITARY OPERATIONS.

128a.7 PROCESSES AND CONTROLS.

(a) Raw materials
(b) Defrosting of frozen fish
(c) Presmoking operations

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

(c) Presmoking operations (Cont'd.)
(1) ----
(2) ----
(3) ----
**(4) Hot processed smoked fish shall be brined in such a manner that the final salt (sodium chloride) content throughout the finished product, expressed as percent in the water phase, shall not be less than that specified in Subpart B.
(5) ----
(d) Heating, cooking, smoking operation
(1) ----
**(2) (Delete from this subsection)
(e) Packing
(f) Testing

**Subpart B-Smoked Fish--
Processing Requirements for Individual Products

Sec.
128b.1 Smoked chub.
128b.2 (e.g. - Smoked sable fish).
128b.3 (e.g. - Smoked salmon).
128b.4 (e.g. - Smoked whitefish).
(Note: above 3 subsections to be inserted as new methods are developed and accepted).
128b.5 All other products.

128b.1 SMOKED CHUB.

(a) Hot processed smoked chub shall be:
(1) Brined in such a manner that the final salt (sodium chloride) content in the water phase of the loin muscle of the finished product shall not be less than 3.5 percent, and heated in such a manner to assure a continuous temperature throughout each fish of 180° F. or above for a minimum of 30 minutes, or
(2) Hot processed smoked chub shall be processed utilizing sodium nitrite in accordance with the procedures prescribed in 121.1230.

NOTE: **These sections illustrate major changes in format of the proposed GMP.

A-664

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

NATIONAL FISHERIES INSTITUTE, INC.

1225 CONNECTICUT AVE., N.W. ◻ WASHINGTON, D. C. 20036 ◻ (202) 223-3161

November 21, 1969

Miss Beryl S. McCullar
Hearing Clerk
Department of Health, Education and Welfare
Room 5440 - 330 Independence Ave., S.W.
Washington, D.C. 20201

Dear Miss McCullar:

Re: Proposed promulgation of regulations to establish criteria for current Good Manufacturing Practice (Sanitation) for Smoked Fish.

The attached comments are submitted by the National Fisheries Institute on behalf of its members on the proposal of the Commissioner, published in the Federal Register of October 23, 1969, (34 FR 17176), to promulgate regulations to establish criteria for current Good Manufacturing Practice (Sanitation) in the manufacture, processing, packing or holding of hot smoked fish to affect compliance with Section 402(a)(4) of the Federal Food Drug and Cosmetic Act.

Sincerely,

NATIONAL FISHERIES INSTITUTE

Ted D. Sanford
Director Technology

Lee J. Weddig
Executive Director

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

COMMENTS ON SMOKED FISH G.M.P.

The National Fisheries Institute has noted the proposed regulations setting forth the specific manufacturing practice (sanitation), requirements regarding hot processed smoked fish in the FEDERAL REGISTER of October 23, 1969.

The National Fisheries Institute represents 48 firms that are vitally interested in smoked fish. Twenty-six of these firms are actively smoking fish. The remainder are either suppliers of raw material or marketing outlets. The industry is very desirous of having a Good Manufacturing Practice Regulation for hot smoked fish and will cooperate in every way possible to make hot smoked fish safe.

As background to these comments, it is important to note activity during the past several years.

In the last five years, the group of plants producing the majority of smoked fish in the United States have made significant capital expenditures, involving structural changes and new equipment, in an effort to improve product quality and wholesomeness. At least two firms are building entirely new plants, incorporating recommended hygienic safeguards. Practices in processing are becoming standardized with increased emphasis being devoted to quality control.

However, the industry is aware of the need of a uniform code of sanitary standards and welcomes the proposed regulation insofar as it applies to sanitation, as an aid in minimizing public health hazards. We believe this will accelerate current improvement programs throughout the industry. However, due to the differences in characteristics of various species sold in smoked form, and due to the fact that the consuming public demands a certain standard of quality for a diversity of product forms, different operating processing parameters are required for each species

of fish.

It has been found for example that smoked chub products acceptable to consumers cannot be prepared in commercial quantities by heating during processing to 180°F for 30 minutes. This has been resolved however by means of a food additive petition permitting the use of nitrite and a specified level of salt, and a lower operating temperature which provides the safety required by preventing the outgrowth of botulinum even under abusive incubating conditions. This petition however restricts the use of nitrite and lower smoking temperatures to a single specie of fish, namely chubs.

As it was found with chubs, it is also impossible to subject other species of fish to the operating temperatures contained in the proposed regulation and have a product acceptable to the consumer.

Although specific safe operating parameters for these other species of fish that are commonly smoked have not yet been established, work now under way by the Bureau of Commercial Fisheries on three species of fish (whitefish, sable and salmon) is showing encouraging preliminary results. The experminental data indicates that considerably lower temperatures in combination with specific salt and nitrite levels will result in a smoked fish product that will be acceptable to the consumer, and also adequately minimize the risk of the public health hazard from Type E botulism. Other preservatives are also being considered.

In view of the unacceptable time temperature parameter of 180°F for 30 minutes, we request that the parameter of 150°F for 30 minutes and 5% salt in the water phase be established as an alternate procedure to that stated in the proposed regulation for an interim period until specific parameters can be established.

This request is predicated on data that indicates that products manufactured using these parameters are safe and marketable.

We would suggest therefore that the present regulation be limited to sanitation principles only and that processing parameters be enumerated on a specie basis.

The processing parameters have been enumerated for chubs and can be referred to. For the other species for which data do not exist during the interim development period processing parameters of either 180°F for 30 minutes with 3½% salt or 150°F for 30 minutes with 5% salt can be used.

As scientific information is developed which indicates other safe operating parameters, specific processing requirements can be issued separately as separate petitions, and be made a part of, and cross referenced to the Smoked Fish GMP.

The food additive regulation published in the FEDERAL REGISTER, Vol. 34, No. 163, August 26, 1969, is a precedent for this. The desire of the smoked fish processors is two fold. First: that the promulgated regulations assure safety for the consumer. Secondly: that conditions and practices established by such regulations can be accomplished by industry.

The basic change in policy suggested above will enable this. Then, in addition, the National Fisheries Institute suggests changes in the proposed rule making to clarify certain ambiguities:

128aIa Add at end: "or by treatment with a concentrated solution of wood smoke."

or: "or by treatment with a solution of wood smoke condendate."

or: "or by treatment with a solution of material resulting from the condensation of wood smoke."

While to our knowledge, no smoked fish is being produced using the above method, there are several reasons why it might be extremely desirable to do so, and it should be provided in the GMP as an alternate method. A large percentage of smoked meat products are so made.

128a1(d) Revise as follows:

Hot processed smoked fish, as used in this part "hot processed smoked fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraph (a) of this section to a drying and heating operation, such that the temperature of the product would reach 100° or higher.

We have purposely ommitted any reference to the salt content and the use of nitrite. These are operating parameters that we feel should not be included with the sanitary regulations. The above differentiates "Hot smoked fish" from "Cold smoked fish". The latter cannot be heated to a temperature over 90° F. or it will take on a cooked quality that is not wanted in cold smoked fish.

128a3b Revise as follows:

The following processes shall be carried out in separate rooms, areas or facilities so arranged to preclude contamination of product from that in earlier stages of processing:

1. Receiving
2. Storage of raw fish
3. Presmoking operations (thawing, dressing & brining, etc.)
4. Drying and smoking
5. Cooling and packing
6. Storage of finished product
7. Shipping

The partitioning of some existing plants into the number of rooms specified cannot be accomplished. Processing can be carried out in a completely sanitary manner without all of the specified rooms. Further, the provision of the specified rooms does not insure completely sanitary processing.

128a3c Revise as follows:

The processing of product shall be conducted in such a manner as to prevent contamination by areas, equipment or utensils involved in earlier processing steps.

128a6b Revise as follows:

Containers being used to convey or store smoked fish or fish products in process shall not be handled in a manner conducive to direct or indirect contamination of the contents.

128a7a4 Revise as follows:

All fish received in a frozen state shall either be thawed promptly and processed or stored at a temperature that will maintain it in a frozen state.

Frozen fish is delivered in various ways and may be at a temperature above 0° F. Frozen fish is usually delivered to a plant for immediate or very early processing and it is usually advantageous to allow it to partially thaw previous to the actual thawing. As written, if literally enforced, this section would prohibit this practice. There is no

bacteriological basis for this. Fish in storage usually are maintained and transported over long distances at temperatures of at least 0° F. and sometimes much lower.

128a7b1 Revise as follows:

i Frozen fish shall be thawed in air or water in such a manner that the temperature of the fish does not exceed 45° F.

ii Delete

128a7b3 Revise as follows:

Add: "excepting inner wrapping material that is frozen solidly against the fish and cannot be readily removed until the fish is thawed.

It is thoroughly impractical, if not impossible, to remove the inner lining material from frozen fish, whether it be paper, plastic or parchment. This addition would make the operation possible and would not add to the contamination as the inner liner is protected by the outer container.

128a7ba Revise as follows:

After fish is thawed it shall be adequately washed,preferably by a spray system.

There should be optional methods of washing fish after thawing. Fish of different sizes require different methods.

128a7c4 Revise as follows:

Hot processed smoked fish shall be brined in such a manner that the final salt (sodium chloride) content throughout the finished product expressed as the salt content of the water phase shall not be less that that specified herein.

128a7d2 Hot processed smoked fish shall either contain not less than 3½% salt (sodium chloride) in the water phase thoughout the product and shall be heated by a process that will insure a continuous temperature throughout each piece of fish of at least 180° F. for at least ½ hour or shall contain not less than 5% salt in the water phase throughout the product and be heated by a process that will insure a continuous temperature throughout each piece of at least 150° F. for at least ½ hour, except that smoked chub containing sodium nitrite as provided for in 121.1230 of this chapter shall be processed in accordance with that section.

128a7e3 Revise as follows:

The finished product shall be cooled to a temperature of 50° F within three hours after smoking and further cooled to a temperature of 38° F within 12 hours after smoking.

The requirement of cooling the hot fish to 38° F. in three hours would require extensive installation of refrigeration equipment in all smoked fish plants. The suggested change would permit most of them to operate with existing equipment. There seems to be no bacteriological basis for the severe cooling requirement.

128a7f1 Revise as follows:

The finished product shall be examined microbiologically with sufficient frequency to assure that processing steps and sanitation of procedures are adequate.

The above would cover the intent with regard to monitoring the sanitation of a smoked fish operation.

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

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HEARING CLERK DEPT OF HEALTH EDUCATION AND WELFARE
WASHDC

THE FOOD AND DRUG PROPOSAL CONCERNING PROCEDURES TO BE APPLIED TO THE SMOKED FISH INDUSTRY AS IN 21CFR PART 128A WOULD CAUSE EXTREME BUSINESS HARDSHIP REQUEST AT LEAST 60 DAY POSTPONEMENT OF THIS REGULATION TO GIVE INDUSTRY A CHANCE TO BE HEARD
MUTUAL FICC

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DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Charleston, Ore

Dear Lois

I have a copy of your new proposed rules to smoking fish.

We have a very small plant doing mostly custom work. We try to do so under clean conditions. The brining process you outlined would not be easy as some of our customers are on salt free diets. These people request their fish smoked with about 1/4th the amount of salt.

We can the greater amount of our smoked fish. This will keep to ship without refrigeration.

The cooling of smoked fish from 180° down to 38° is a bit rapid. (3 hours)

This part of separate rooms for each operation is going to be rough on small plants with only one or two

rooms to work in.

Sheer recording thermometers are also expensive to buy and install. The brining process at 38° will be a bit difficult at all times. We do not hold our smoked fish for as long as one week before it is packed in tins & cooked

Hoping you will try to work out rules to help us all. Also to let us stay in business.

Yours

Elwin L. Edwards

address Ret Envelop Chucks Seafood Market
Box 5370
Charleston, Oregon, 97420

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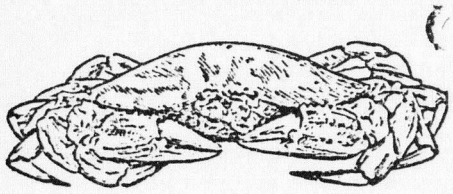

BELL BUOY CRAB COMPANY

Quality Sea Foods

We Specialize in Fresh and Canned Crabs

P. O. Box 46 -:- SEASIDE, OREGON
Phone Area Code 503 REdfield 8-6354

November 13, 1969

Hearing Clerk
Dept. of Health, Education, & Welfare
Room 5440
330 Independence Ave., S. W.
Washington, D. C. 20201

Dear Sir:

We have recently received information from the Federal Register, Vol. 34, No. 204-Thursday, October 23, 1969 pertaining to Smoked Fish and Seafood Products.

We feel that this proposed legislation will put the smaller place that smoke and kipper fish out of business, at least out of the Kippering business. Perhaps the larger Smoke Fish places that smoke many tons per day can afford to make the proposed changes, but the smaller producers cannot.

It is our understanding that some time ago bacillis botullinus was found in some white fish that was kippered in the Lake Michigan; however we have been kippering for over 20 years, and after the Lake Michigan poison was found, the Pure Food and Drug people made inspections of about 15 pounds of our kippered fish three times, about three weeks apart, and found everything to be O. K. In fact the Pure Food and Drug Administration people have made inspections here all through these years without any adverse reports. We do not believe that all of these precautions are necessary.

We will appreciate any action that you can take in this matter.

Yours very truly,

E. Engelson, Mgr.
Bell Buoy Crab Co.

CC: Ken Hilderbrand
O.S.U. Seafoods Lab.
250 36th St.
Astoria, Oregon 97103

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

OSU

COOPERATIVE EXTENSION SERVICE

MARINE ADVISORY PROGRAM
OSU SEAFOODS LABORATORY
250 36th St.
ASTORIA, OREGON 97103

Phone: 325-6138

November 12, 1969

Hearing Clerk
Dept. of Health, Education & Welfare
Room 5440
330 Independence Ave., S.W.
Washington, D.C. 20201

Dear Sir:

I would like to comment on the Good Manufacturing Practice proposed by the FDA in the October 23, 1969 issue of the Federal Register (Vol. 34, No. 204).

1. The GMP would not seem to include the "cold smoked" fish products which are preserved by salt and low moisture. It would therefore seem helpful to give guidelines for differentiating between "cold smoked" and "hot process" smoked fish.

2. The GMP does not clearly exclude "canned" smoked fish (hermetically sealed and retorted). The provisions of the GMP are not applicable to this product and should therefore specifically exclude fish prepared for this purpose.

3. 128 a.3 - Plants & Grounds. This provision may cause hardship on processors at boat unloading docks which are frequently made of wooden planks. At these unloading facilities the fish are handled in containers and the fish do not contact the wooden surface.

4. 128 a.7 - Processes & Controls.

b) The maximum holding period (in a tank) of 1/2 hr. after thawing requires a judgement as to when the fish are actually thawed. In many cases, due to water temperature and variation in fish size, this judgement will be very difficult if not impossible. There is no true freezing or melting (thawing) point in a fish.

c) Presmoking operation:

3) The requirement of "brining" in 30°F. or less "brine" would seem to rule out "dry salting" techniques. The use of "dry salting" seems to be desireable to certain processors and should not be prohibited when minimum salt content requirements can be met.

d) Heating, cooking, smoking operation:

1)and 2) These requirements for continuous monitoring, recording, and controlling can not be accomplished in practice. The use of a recorder to monitor internal temperature of fish would be subject to

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

variations in fish size and placement of the thermocouple. One recorder with a thermocouple placed properly in the smoke house should suffice. The process time and temperature should be designed to insure proper heating. More study is needed before specific requirements can be made. At this point it might be better to try to set certain minimum performance standards for the smoke houses themselves.

f) Testing:

1) As with most small food businesses, most smoked fish processors will not be able to afford the cost of a laboratory facility for microbiological testing. This provision seems to put smoked fish processors at a disadvantage in many coastal areas where outside services are not readily available. Periodic testing and inspection by state and Federal agencies should suffice.

Yours truly,

Ken Hilderbrand
Seafood Technologist

KH:ls

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 128a]

34 FR 17176
10/23/69

HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING

PROPOSAL RE SMOKED FISH

Observation in smoked fish processing plants by the Food and Drug Administration and other regulatory agencies since 1963 has shown that the smoked fish industry has not consistently adhered to manufacturing practices that would minimize the hazard of Type E botulism and the risks of food-borne infections in the consumption of smoked fish.

The Bureau of Commercial Fisheries, Department of the Interior, has suggested that adequate times and temperatures along with salt concentrations have not yet been established for each individual species smoked other than smoked chub. The Bureau provided recommendations that proposed regulations be limited to plant sanitation, excluding reference to processing techniques that would (1) deal with time-temperature relationships or (2) describe good manufacturing techniques for smoked chub as processed in accordance with the food additive regulation § 121.1230 Sodium nitrite used in processing smoked chub (34 F.R. 13659). that would pertain only to smoked chub

The Food and Drug Administration acknowledges that adequate

(page 1A follows)

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked. Much work has been done, however, on the thermal destruction of spores of Clostridium botulinum Type E, and to date the processing parameters presented in the proposal are the safest known from the standpoint of preventing outgrowth and toxin formation of C. botulinum Type E. It has been established that the public health hazard of C. botulinum Type E in smoked fish is not restricted to a single species. Examples of species found to contain spores of C. botulinum Type E are lake trout, salmon, black cod (sablefish), sole, sturgeon, and whitefish.

The FDA has been, is, and will continue to be receptive to scientific data that documents adequate processing parameters or offers alternate processing parameters for any individual species of smoked fish. Data must be provided showing that the proposed processing parameters adequately minimize risks of the public health hazard of poisoning by Type E botulism.

Currently, the situation exists whereby some processors base their manufacturing practices solely on the appearance and acceptability of the finished product quality to consumers rather than on any specific or controlled processing parameters that would minimize the health hazard of C. botulinum Type E or its toxins.

(page 1B follows)

DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Having considered the foregoing, the Commissioner of Food and Drugs proposes the following regulations setting forth specific manufacturing practice (sanitation) requirements regarding hot processed smoked fish.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that the following new Part 128a be added to Chapter I of Title 21:

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PART 128a--FISH AND SEAFOOD PRODUCTS

SUBPART A--SMOKED FISH

Sec.

128a.1 Definitions.

128a.2 Current good manufacturing practice (sanitation).

128a.3 Plants and grounds.

128a.4 Equipment and utensils.

128a.5 Sanitary facilities and controls.

128a.6 Sanitary operations.

128a.7 Processes and controls.

AUTHORITY: The provisions of this Part 128a issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a))

§ 128a.1 Definitions.

(a) Smoked fish. As used in this part, the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the action of smoke from burning wood, sawdust, or similar material.

(b) Loin muscle. As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the medium superficial muscle.

(c) Water phase salt. As used in this part, "water phase salt"

means the percent salt (sodium chloride) in the finished product as determined by the method prescribed in the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th Edition, 1965, page 273, under paragraph 19.009, multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method prescribed under paragraph 18.006.

(d) Hot process smoked fish. As used in this part, "hot process smoked fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraph (a) of this section to heat to cook it. The finished hot process smoked product contains not less than 3 1/2 percent salt (sodium chloride) in the water phase of the loin muscle as determined by the methods prescribed by paragraph (c) of this section. The food additive sodium nitrite may be used in accordance with the conditions prescribed by § 121.1230 of this chapter.

§ 128a.2 Current good manufacturing practice (sanitation).

(a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this Subpart A set forth additional

requirements for the hot process smoked fish industry.

§ 128a.3 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Receiving or shipping.

(2) Storage of raw fish.

(3) Presmoking operations (thawing, dressing, brining, etc.).

(4) Drying and smoking.

(5) Cooling and packing.

(6) Storage of final product.

(c) The product shall be so processed as to prevent contamination by exposure to areas involved in earlier processing steps, refuse, or other objectionable areas.

§ 128a.4 Equipment and utensils.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature measuring devices shall have an accuracy of $\pm 2^{\circ}$ F.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store the fish shall not be nested or handled in a manner conducive to direct or indirect contamination of the contents.

(c) Adequate measures shall be taken when cleaning and sanitizing utensils and portable equipment to prevent this operation from leading to the contamination of fish or fish products.

§ 128a.7 Processes and controls.

(a) Raw materials. (1) Fresh fish shall be adequately washed and inspected to remove all fish that are filthy, putrid, decomposed, bruised, crushed, or otherwise damaged.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish shall be chilled with ice or refrigerated to an internal temperature of 38° F. or below when received and shall be maintained at that temperature until the fish are to be processed.

(4) Frozen fish shall be received and stored at a temperature of 0° F. or below.

(b) Defrosting of frozen fish. (1) Frozen fish shall be defrosted:

(i) In air at 45° F. or below until other than hard frozen; or

(ii) In a continuous water overflow thaw tank or spray system using water not greater than 70° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than 1/2 hour after they are thawed.

(3) Fish entering the thaw tanks shall be free of packaging material.

(4) On removal from the thaw tank, fish shall be washed throughly with a vigorous water spray.

(c) Presmoking operation. (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish shall be thoroughly washed by means of a continuous spray system.

(3) All fish shall be brined in a solution that does not exceed 38° F.

(4) Hot process smoked fish shall be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than 3.5 percent.

(5) Fish shall be rinsed with fresh water after brining.

(d) Heating, cooking, smoking operation. (1) A point-sensitive, continuous temperature recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the smokehouse.

(2) Hot process smoked fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of 180° F. or above for a minimum of 30 minutes for hot process smoked fish, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section.

(e) Packing. (1) The finished product shall be handled only with clean, sanitized hands or gloves.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to 38° F. or below within 3 hours after smoking, and this temperature shall be maintained during all subsequent storage and distribution.

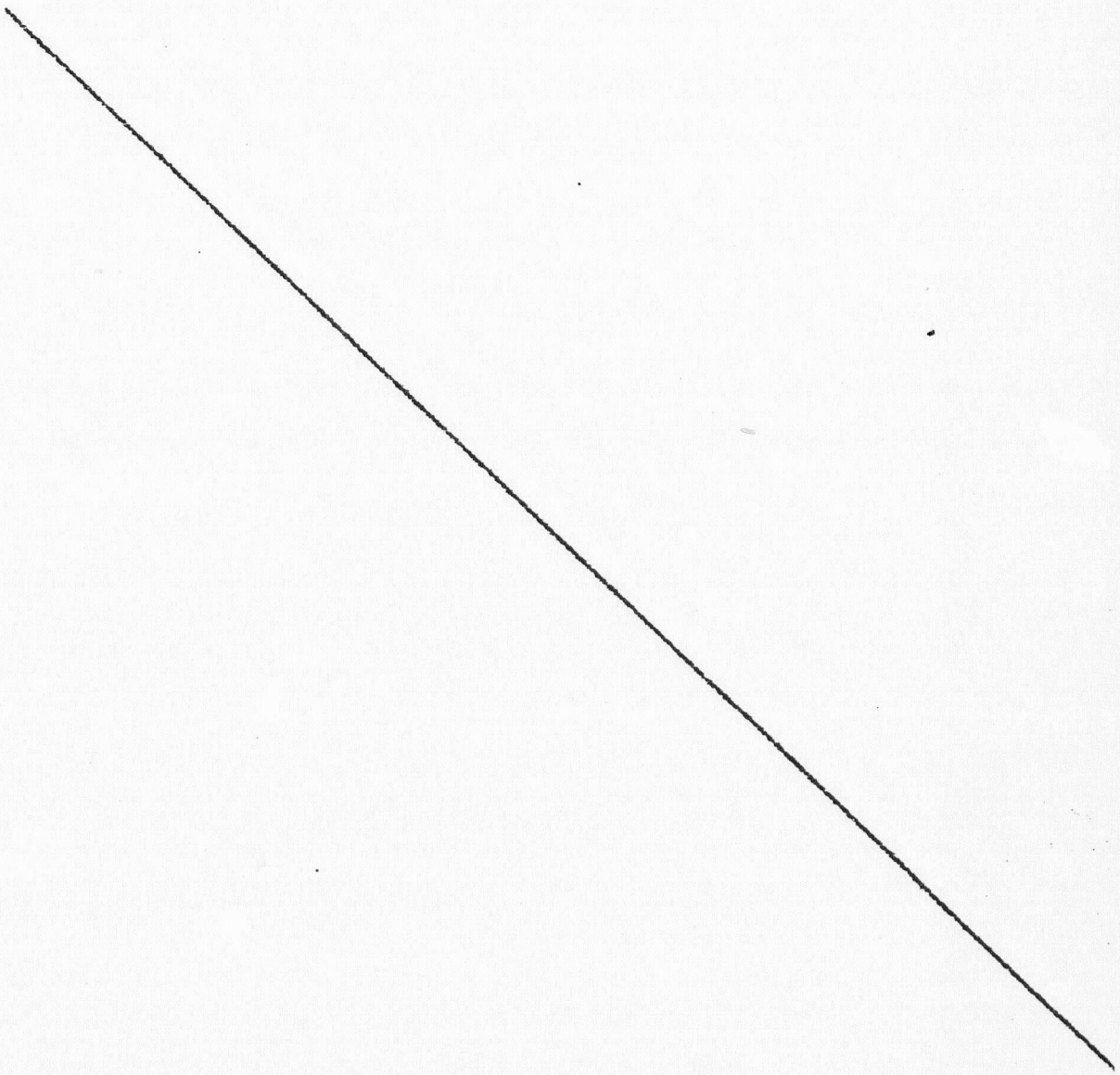
(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F. or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks should show at least the date of packing and the plant where packed.

(f) Testing. (1) The microbiological condition of the firm's operation shall be evaluated by the periodic collection and analysis of in-line and finished product samples coupled with

sample-related inspections. This evaluation should be made at least weekly and more often when problems are encountered.

(2) The finished product shall be examined for salt content with sufficient frequency to assure that the required salinity is obtained in every fish.



DEFENDANTS' EXHIBIT D - TAB A OF THE PURPORTED ADMINISTRATIVE RECORD

Any interested person may, within 30 days from the date of publication of this notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: OCT 16 1969.

J. K. Kirk,
Associate Commissioner
for Compliance.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Elmer B. Black

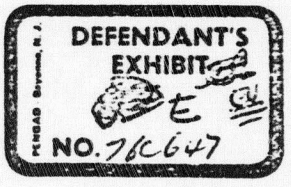
DEFENDANTS' EXHIBIT E - LETTER DATED DECEMBER 23, 1970 FROM RICHARD S. MOREY, ESQ. TO FRANK THOMPSON, DIVISION OF COMPLIANCE PROGRAMS, FOOD AND DRUG ADMINISTRATION

COVINGTON & BURLING
888 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20006

TELEPHONE
(202) 293-3300

TELETYPE: (202) 965-0673
CABLE: COVLING

December 23, 1970



Mr. Frank Thompson
Division of Compliance Programs
Bureau of Foods, Pesticides, and
Product Safety
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Thompson:

This will confirm, on behalf of the National Fisheries Institute and the Association of Smoked Fish Processors, Inc., the comments made to you and the other FDA representatives at the December 15, 1970 meeting as to the good manufacturing practice regulations for smoked and smoke-flavored fish. In addition, it includes such supporting material as is presently available with respect to the industry's proposed changes to these regulations.

Initially, we refer to the meeting between industry representatives and General Delmore and other FDA representatives held on April 7, 1970 to discuss these regulations. It was the industry's understanding that further meetings would be held between technical representatives of the industry and FDA's scientific personnel to discuss the processing requirements contained in the proposed regulations, before final regulations were promulgated. As you know, no such meetings were held prior to the

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promulgation of the final order establishing these regulations. It is the industry's position that the present regulations are in need of revision and that further discussion at this time still would be useful and could lead to regulations which meet both industry's capabilities and FDA's public health responsibilities. Accordingly, we submit the following comments.

I. PRESENT INDUSTRY STATUS

A. Processing Requirements. On December 1, 1970, a meeting of the smoked fish industry was held to discuss the good manufacturing practice regulations for smoked and smoke-flavored fish which became effective on December 13, 1970. Technical representatives and legal counsel for the National Fisheries Institute and the Association of Smoked Fish Processors, Inc. advised industry members to comply with these regulations in all possible respects as quickly as could be done. Industry members reported that they were already working toward achieving compliance based on the proposed regulations. They also reported, however, that the final regulations contain a number of requirements which are impossible to meet and should be changed.

The industry representatives noted particularly that the processing requirement of 180° F. for 30 minutes simply could not be met, except for one species of fish. They said that FDA observers had visited their plants, had attempted to meet this

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requirement and were unable either to do so or to suggest any manner in which the industry could do so. In addition, they noted that while certain processors had reported in certain instances that they had achieved these processing parameters, no industry member in fact had been able to produce salable smoked fish under conditions in which the coolest fish in the smokehouse had reached a temperature of 180° and held this temperature for a full 30 minutes. It also was noted that the industry was unaware of any equipment with which they could meet the 180° -30 minute requirement or come substantially closer to this requirement than was possible with existing equipment. Those industry members with the most modern equipment available still are unable to meet the 180° -30 minute requirement.

B. Brining Requirements. Industry representatives reported that the salt concentration requirements contained in the regulations were difficult to meet, both the 3.5 percent concentration and the 5 percent concentration. They noted that this difficulty is accentuated by the requirement in the regulations that the brining temperature be maintained at 38° F. rather than 50° F. as recommended by the industry because salt uptake is somewhat better at 50° F. They also suggested that the requirement for rinsing the fish after brining caused a reduction in salt content due to leaching of the salt out of the fish into the rinse water.

C. Temperature Recording Requirements. The requirements contained in the regulations for monitoring of temperature of both the smokehouse and the fish,

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industry representatives suggested were unworkable. Systems for monitoring internal fish temperature are not adaptable to the industry's processing requirements because the attaching of probes to the fish to measure internal temperature prevents normal rotation of the fish racks during smoking.

D. Separate Room Requirement. Finally, it was pointed out that at least one processor was not able to meet the mandatory separate room requirement contained in Section 128a.3(c).

II. INDUSTRY PROPOSALS

A. Processing Requirements. The industry recognizes that all processing requirements contained in FDA's good manufacturing practice regulations must be based on public health considerations. It is also recognized that these requirements cannot be reduced simply because the industry is unable to meet them. Such requirements should, however, be as flexible as possible to afford the industry as many alternative processing parameters as can be justified, based on public health considerations.

In this regard, the industry notes that it has been well established that a combination of salt and sodium nitrite is effective in inhibiting the outgrowth of botulism in smoked fish. As the FDA Fact Sheet on "Nitrites, Nitrites and Nitrosamines" dated November 25, 1970 states:

> "nitrite serves a particular useful perser-vative function by inhibiting the outgrowth

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COVINGTON & BURLING

of heat sensitized botulinum spores in semiperishable products such as smoked fish . . ."

The effectiveness of the combination of salt and nitrite is even more clearly demonstrated in the food additive petition upon which 21 C.F.R. Section 121.1230, allowing the use of sodium nitrite in processing smoked chub, is based. The data contained in this petition also demonstrate that even the 180 ° -30 minute requirement contained in the present regulation is not always effective in suppressing outgrowth of Type E botulism. Taken as a whole, the data in this petition strongly suggest that a combination of salt and nitrite is more important than temperature in controlling outgrowth of Type E botulism.

Based on the evidence contained in the smoked chub petition, it is recommended that FDA establish alternative processing parameters recognizing the inhibitory effect of sodium nitrite in all species of smoked fish in which this substance may be used. Specifically, 21 C.F.R Section 121.1064 allows the use of sodium nitrite as a preservative and color fixative in smoked sable fish and smoked salmon at the same level at which this substance is used in smoked chub to aid in inhibiting the outgrowth of Type E botulinum. Since the data in the petition submitted with respect to smoked chub strongly suggest that this substance also would be effective in other species of smoked fish (as is also indicated in the FDA Fact Sheet), it is recommended that alternative processing parameters be established for smoked salmon and smoked sable fish containing sodium nitrite.

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The industry presently does not have data indicating the precise processing parameters which should be established for smoked salmon and smoked sable. This work is being done for the industry by the National Marine Fisheries Service and will be submitted to FDA as soon as it becomes available. In the interim, however, the industry recommends that a processing parameter of 150 ° F for 30 minutes with 3-1/2 percent salt and between 100 and 200 ppm sodium nitrite be established. The data from the petition for the use of nitrite in smoked chub suggest that these would be workable parameters for use in these additional species as well.

Sodium nitrite presently is not a permitted ingredient in smoked whitefish. The National Marine Fisheries Service, however, has been engaged in experiments establishing the usefulness of this substance in whitefish with a view toward submitting a petition to establish a food additive regulation to permit its use. Industry representatives are informed that NMFS has completed the work with respect to DMNA on this project, and that the food additive petition will be filed in about 30 days. This petition, in addition to establishing workable processing parameters for smoked whitefish, will confirm the effect of sodium nitrite as an inhibitory agent against Type E botulinum, and will further corroborate the usefulness of this substance in smoked sable and smoked salmon, as well as in smoked whitefish.

As was pointed out by industry representatives at the April 7, 1970 meeting, processing requirements for different species of smoked fish simply cannot be lumped together. Each species of smoked fish

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has individual characteristics as to the temperature under which it may be processed. We will, therefore, discuss the present status of each of the major species of smoked fish, noting the temperature conditions which the industry can meet and the realistically available processing parameters.

1. Chub. The industry is able to process smoked chub at 150 to 160 ° F. C.F.R. Section 121.1230 permits the use of sodium nitrite in this species to inhibit Type E botulinum and provides workable processing parameters. Since the regulations specifically recognize these alternative parameters for smoked chub, the processing of this species does not present a substantial problem to the industry.

2. Sable. The industry is able to process smoked sable to between 140 and 150 ° F. Of all the species of smoked fish, sable also is the only one which can achieve a 5 percent salt concentration under normal processing conditions, although with difficulty. This provides one possibly workable set of processing parameters for the product (150 ° F. for 30 minutes, 5 percent salt). The recognition of an additional set of processing parameters based on the use of sodium nitrite with 3.5 percent salt at 150 ° F. would provide an additional set of processing parameters that would alleviate the difficulty in reaching the 5 percent salt concentration.

3. Salmon. Smoked salmon can be processed to approximately 150 ° F. The establishment of additional processing parameters based on the use of sodium nitrite (with 3.5 percent salt, 150 ° F. for 30

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minutes) for this species would alleviate present processing difficulties.

4. Whitefish. Whitefish can be processed to approximately 150 to 160 ° F. Work is almost completed on a food additive petition to allow the use of sodium nitrite in this species. Establishment of processing parameters based on the use of sodium nitrite also would alleviate processing difficulties as to this species.

5. Sturgeon. Smoked sturgeon is presently the only major species of smoked fish which can meet the 180 ° -30 minute requirement without difficulty.

B. Brining Requirements. The industry continues to recommend that the brine temperature requirement be amended to allow the use of brine up to 50 ° F. rather than 38 ° F. As shown in the work of Weckel and Wosje, which was available to FDA at the December 15, 1970 meeting, an increase in the temperature of brine increases the rate of absorption of salt into the total edible portion of the fish. The difference is not a striking one but in some instances may make a difference in whether a processor can reach the 3.5 percent and 5 percent salt requirements. Thus, so long as the recommended increased temperature does not create a serious hazard of Type E botulinum outgrowth, it should be allowed.

Research by Segner, Schmidt and Boltz, 1966, Applied Microbiology 14: 49-54, found outgrowth time for Type E botulinum to be 10 to 12 days at 49 ° F. in

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one instance and 4 days at 50 ° F. under other conditions. Since the outgrowth times observed in these experiments were under optimal conditions for the growth of Type E organisms, a considerably longer outgrowth in time could be expected for fish in a concentrated brine solution. The work of Hobbs, Cann and Wilson, 1969, Journal Food Technology 4: 185-191, confirms the Segner study. This study showed that in Atlantic herring, toxin was first detected in 4 to 7 days at 50 ° F. In smoked kippers and haddock, toxin was first detected at 8 and 28 days of incubation respectively at 50 ° F.

All of this material strongly suggests that there is little, if any, hazard involved in maintaining fish in concentrated brine at 50 ° F. for less than 4 days. Since the fish in fact are normally in the brine for only 12 to 18 hours, the hazard involved is minimal. To provide even further safety, industry representatives suggested at the December 15, 1970 meeting that the brined fish be introduced into a cool room which would reduce the temperature of the fish and brining solution to at least 38 ° F. in 12 to 18 hours. If the fish are occasionally brined for longer than 18 hours, this cooling will insure continued protection against toxin production.

Based on this data, the industry believes that a requirement for brining at 50 ° is fully justified because of the added salt absorption provided and the lack of any demonstrated health hazard.

As to the rinsing requirement after brining, it developed during the December 15, 1970 meeting that FDA interprets this to require merely a spray

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rinse which will not cause any leaching of salt from the fish. So interpreted, the industry has no difficulty with this requirement.

C. Temperature Recording Requirements. Because of the impracticality of requiring continued monitoring of internal fish temperature as well as ambient oven temperature, industry representatives suggest that the regulations be amended to allow the monitoring only of ambient oven temperature for any processor who develops data showing that the ambient oven temperature predicts the internal temperature of the fish being smoked in the oven. This would provide assurance to FDA that the fish in fact were being processed at the proper temperatures without imposing a difficult and unnecessary requirement on the processor.

D. Separate Room Requirement. For industry members whose present plant layout cannot be adapted to meet the separate room requirement of Section 128a.3(c), the industry recommends the adoption of a "scheduling" alternative to this requirement. This would permit a processor who could not adapt his plant to the requirements to continue operations so long as he carefully avoids the possibility of cross-contamination between different processing steps by scheduling these steps at different times and adequately sanitizing the area between operations.

III. CONTINUED INDUSTRY EFFORTS

The smoked fish industry is making every effort

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to develop additional data as quickly as possible, justifying the amendments which it has suggested in the regulations. Since much of the work (all of the work on sodium nitrite) must be done by the National Marine Fisheries Service which presently is in the midst of reorganization, such data simply cannot be produced instataneously. The information will, however, be produced as expeditiously as can be done under the circumstances, and will immediately be made available to FDA.

Industry representatives also are ready to meet with FDA representatives in the interim to discuss further the changes in the regulations proposed herein or any other aspect of these regulations, if FDA believes this would be helpful. The industry views compliance with the good manufacturing practice regulations as an extremely serious industry-wide problem. It will make every effort both to comply with the present regulations and to cooperate with FDA in instituting necessary changes in the regulations.

Any FDA comments with respect to the industry's proposed changes in the regulations or compliance with the present regulations should be addressed to the undersigned.

Yours very truly,

Richard S. Morey

Richard S. Morey

Counsel for National Fisheries Institute

cc: All interested members of National Fisheries Institute and Association of Smoked Fish Processors, Inc.

DEFENDANTS' EXHIBIT P - PAGES 63-64 FROM BOOK ENTITLED SIXTY FIVE YEARS OF HUMAN BOTULISM IN THE UNITED STATES AND CANADA

BOTULISM IN THE UNITED STATES AND CANADA

Total Outbreaks by Year and by Home- and Commercially-processed Foods

Year	Home Processed & Home Canned		Commercially Canned		Unknown	Total Outbreaks
	Bacteriologically Proven*	Bacteriologically Not Proven	Bacteriologically Proven*	Bacteriologically Not Proven		
1899-1909	0	2	0	1	0	3
1910	1	1	0	1	0	3
1911	0	0	0	0	1	1
1912	1	3	0	2	0	6
1913	0	3	0	1	2	6
1914	1	1	1	0	0	3
1915	2	2	0	3	0	7
1916	4	1	0	0	2	7
1917	4	3	0	0	0	7
1918	6	6	0	3	1	16
1919	1	7	3	2	2	15
1920	0	3	4	6	1	14
1921	6	3	5	0	1**	15
1922	13	4	1	1	4	23
1923	5	5	0	0	2	12
1924	7	2	2	1	0	12
1925	3	2	3	1	2	11
1926	2	1	0	0	0	3
1927	3	1	0	0	1	5
1928	5	3	0	0	0	8
1929	7	3	1	0	2	13
1930	1	4	0	0	0	5
1931	5	7	1	2	0	15
1932	6	11	1	0	2	20
1933	5	13	0	2	1	21
1934	2	4	1	0	2	9
1935	7	18	0	0	1	26
1936	4	5	1	0	0	10
1937	6	7	0	0	2	15
1938	5	8	0	1	2	16
1939	6	10	0	0	2	18

* Proven by culture and/or fowl or animals
** Proven from brain tissue of patient

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Year	Home Processed & Home Canned		Commercially Canned		Unknown	Total Cut-breaks
	Bacterio-logically Proven	Bacterio-logically Not Proven	Bacterio-logically Proven	Bacterio-logically Not Proven		
1940	9	8	0	0	1	18
1941	6	8	1	0	0	15
1942	5	8	0	0	3	16
1943	6	5	0	0	2	13
1944	10	10	0	0	2	22
1945	6	5	0	0	3	14
1946	6	1	0	0	2	9
1947	8	10	0	0	2	20
1948	4	7	0	0	1	12
1949	2	2	0	0	3	7
1950	3	2	0	0	7	12
1951	4	4	1	0	4	13
1952	6	4	0	0	3	13
1953	7	3	0	0	3	13
1954	5	2	1	0	3	11
1955	4	1	0	0	2	7
1956	5	4	0	0	1	10
1957	4	3	0	0	1	8
1958	2	2	0	0	1	5
1959	6	2	0	0	2	10
1960	3	7	1	0	0	11
1961	7	4	0	0	3	14
1962	4	4	0	0	0	8
1963	8	2	10	0	0	20
1964	4	1	0	0	0	5
TOTALS	252	252	38	27	82	651

Total Proven: 291
Total Not Proven (including unknowns): 360

DEFENDANTS' EXHIBIT P-1 - PAGES 74-76 FROM BOOK ENTITLED SIXTY FIVE YEARS OF HUMAN BOTULISM IN THE UNITED STATES AND CANADA

BOTULISM IN THE UNITED STATES AND CANADA
DUE TO COMMERCIAL FOOD PRODUCTS
1899 through 1964

Year	State	Food Involved	Out-breaks	Cases	Deaths	Type
1899	--	--	0	0	0	--
1900	--	--	0	0	0	--
1901	--	--	0	0	0	--
1902	--	--	0	0	0	--
1903	--	--	0	0	0	--
1904	--	--	0	0	0	--
1905	--	--	0	0	0	--
1906	California	Pork and beans	1	3	3	
1907	--	--	0	0	0	--
1908	--	--	0	0	0	--
1909	--	--	0	0	0	--
1910	California	String Beans	1	4	4	
1911	--	--	0	0	0	--
1912	California	Clam juice	1	2	1	--
	Colorado	String beans	1	7	5	--
1913	California	Clam juice	1	3	2	--
1914	Washington	Clam juice	1	2	2	--
1915	California	Sausage	1	2	2	--
	Colorado	String beans	1	5	5	--
	Illinois	Tomato catsup	1	2	0	--
1916	--	--	0	0	0	--
1917	--	--	0	0	0	--
1918	California	Corn	1	1	0	--
	California	Olives, minced	1	2	2	--
	California	Tuna	1	1	1	--
1919	Canada	Beets	1	23	12	--
	Michigan	Olives	1	7	5	A
	Montana	Olives	1	7	5	A
	Ohio	Olives	1	14	7	A
	Wisconsin	Summer sausage	1	3	0	--
1920	Arizona	Beets	1	5	5	B
	California	Spinach	1	6	3	A
	California	Olives, minced	1	5	0	A
	California	Olives, minced	1	1	1	--
	California	Olives, ripe	1	1	0	--
	Maine	Ham	1	4	4	--
	New York	Spinach	1	2	2	--
	New York	Olives, ripe	1	1	1	--
	Tennessee	Olives, ripe	1	7	7	A
	Washington	Milk	1	4	0	--

DEFENDANT'S EXHIBIT D-1

DEFENDANTS' EXHIBIT P-1 - PAGES 74-76 FROM BOOK ENTITLED SIXTY FIVE YEARS OF HUMAN BOTULISM IN THE UNITED STATES AND CANADA

Year	State	Food Involved	Out-breaks	Cases	Deaths	Type
1921	California	Spinach	1	1	0	A
	Indiana	Spinach (California packed)	1	2	2	A
	Michigan	Spinach	1	29	3	A
	Michigan	Spinach	1	5	2	A
	Pennsylvania	Olives, ripe	1	5	3	A
1922	Ohio	Spinach	1	2	2	--
	Indiana	Spinach (from California)	1	9	4	A
1923	--	--	0	0	0	--
1924	California	Olives, ripe	1	9	2	A
	California	Olives, ripe	1	6	2	--
	Wyoming	Olives, ripe	1	7	4	A
1925	California	Sardines	1	2	2	--
	Colorado	Spinach	1	5	1	B
	Ohio	Sardines	1	2	2	A
	Wyoming	Meat, potted	1	4	4	B
1926	--	--	0	0	0	--
1927	--	--	0	0	0	--
1928	--	--	0	0	0	--
1929	Illinois	Shallots (Italian)	1	2	1	B
1930	--	--	0	0	0	--
1931	California	Antipasto (Italian)	1	3	1	--
	California	Milk (Suspected)	1	1	0	A*
	Washington	Sardines, with tomato sauce	1	2	1	--
1932	New York	Salmon, smoked (from Canada)	1	3	1	E
1933	California	Crab (Japanese)	1	1	0	--
	Washington	Salmon (suspected)	1	1	1	--
1934	New York	Sprats (German)	1	3	1	E
1935	--	--	0	0	0	--
1936	California	Clams (Japanese)	1	4	4	B
1937	--	--	0	0	0	--
1938	Massachusetts	Tuna (suspected)	1	2	2	--
1939	--	--	0	0	0	--
1940	--	--	0	0	0	--
1941	California	Mushroom sauce (California)	1	3	1	E
1942	--	--	0	0	0	--
1943	--	--	0	0	0	--
1944	--	--	0	0	0	--
1945	--	--	0	0	0	--
1946	--	--	0	0	0	--
1947	--	--	0	0	0	--
1948	--	--	0	0	0	--
1949	--	--	0	0	0	--

* From two stools of infant

DEFENDANTS' EXHIBIT P-1 - PAGES 74-76 FROM BOOK ENTITLED SIXTY FIVE YEARS OF HUMAN BOTULISM IN THE UNITED STATES AND CANADA

Year	State	Food Involved	Out-breaks	Cases	Deaths	Type
1950	--	--	0	0	0	--
1951	California	Liederkranz cheese spread (California)	1	1	1	B
1952	--	--	0	0	0	--
1953	--	--	0	0	0	--
1954	Indiana	Pork barbecue, glass-packed	1	2	0	B
1955	--	--	0	0	0	--
1956	--	--	0	0	0	--
1957	--	--	0	0	0	--
1958	--	--	0	0	0	--
1959	--	--	0	0	0	--
1960	Minnesota	White fish, packed in vacuum-sealed plastic bags	1	2	2	E
1961	--	--	0	0	0	--
1962	--	--	0	0	0	--
1963	Alabama	Smoked white fish in vacuum bags	2	3	0	E
	Canada	Liver paste	1	2	1	B
	Kentucky	Smoked white fish in vacuum bags	1	2	0	E
	Michigan	Smoked white fish in vacuum bags	1	2	2	E
	Michigan	Tuna (from California)	1	3	2	E
	Minnesota	Smoked white fish in vacuum bags	1	1	0	E
	New York	Liver paste (canned in Canada)	1	2	0	A
	Tennessee	Smoked white fish in vacuum bags	2	12	5	E
1964	--	--	0	0	0	--
TOTALS			65	269	138	

DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

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FISHERIES RESEARCH BOARD OF CANADA

Technological Research Laboratory

Halifax, Nova Scotia

D. R. IDLER, *Director*

New Series No. 14 CIRCULAR March 11, 1964

DEFENDANT'S EXHIBIT (D) Q NO. 76 C 647

A REPORT

to the

FISHING INDUSTRY

on the

SIGNIFICANCE OF BOTULISM

in the

CANADIAN FISHERIES

by

C.H. Castell

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DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

FOREWORD

Mr. C.H. Castell obtained his M.S.A. degree from Toronto and joined the Fisheries Research Board of Canada in 1944. He is presently Investigator-in-Charge of the Bacteriology Department and Assistant Laboratory Director.

Mr. Castell's research program has emphasized all facets of fresh fish quality, including vessel and plant sanitation, refrigeration procedures and fish preservation. The results of these investigations have contributed to great improvement in the quality of fresh and frozen fish reaching the consumer.

D.R. Idler, D.F.C., Ph.D.
Director
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Halifax, Nova Scotia

DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

INTRODUCTION

Every once in a while, we read in the daily papers that somewhere in the world there has been an outbreak of botulism. The report usually states that this is a very rare, but often fatal, type of food poisoning.

If it has occurred in some far away country, the event quickly passes from our mind, but if the deaths occur in the United States or Canada, it may leave us with a sense of uneasiness, and we make a mental note of the type of food involved. If we should happen to be a producer of the same type of food as that mentioned in the newspaper report, this sense of uneasiness becomes a very real thing.

To the layman there is something sinister and mysterious about food poisoning. If our friend is knocked down by a tram car or shot in the head by his neighbour, we can see and understand the reason for his death. We rationalize, and say to ourselves: "But that will never happen to *me*. *I* know enough to keep out of the way of tram cars, and *I* have enough sense not to feud with my neighbours", but it is quite different when it comes to food poisoning. This is something that the layman seems to be able to neither avoid nor to control.

The almost panic-like reaction to an outbreak of botulism is not merely because of the fact that the disease can be fatal. Thousands of people are killed each day in automobile accidents and we have no secret dread of a car ride. It is the sense of the mysterious, the unknown, and the unpredictable that disturbs us. We can rid ourselves of this unnecessary fear, and develop a more sensible attitude towards botulism, by becoming better acquainted with the facts that are involved. That is the purpose of this circular.

Over the last fifty years, food scientists have given a great deal of attention to the problem of botulism. There are literally thousands of papers, published in scientific journals all over the world, but this information is not generally available to those who are actually involved in the production of food products. Even if it was available, much of it is written in a language that cannot be easily understood by laymen. It is impossible to summarize and translate into non-technical language all the work that has been done on botulism. An attempt has been made here to provide sufficient information to enable an intelligent fish plant manager to assess the significance of botulism to his operations and to estimate the hazards involved. A list of some important scientific papers on various aspects of botulism has been provided for those who wish to pursue the subject in greater detail.

The term "botulism" has its origin in the Latin word "botulus" which means sausage. There are records showing that "sausage poisoning" was prevalent in Germany at least 250 years ago, long before the time when men had discovered bacteria and established their relationship to the spoilage of food and the production of innumerable diseases. At this early period, the health authorities believed the disease now known as botulism was caused by traces of copper or lead from the containers in which the meats and other ingredients were prepared.

It is interesting to note that almost all these early instances of botulism were the result of people consuming *prepared* or *processed* meats; such as blood sausage. liverwurst or various types of salted or pickled meats. Rarely, if ever, were fresh meats involved.

By the middle of the last century, bacteria had been discovered and various workers in Europe began to theorize that botulism was in some way associated with these microscopic fungi. One theory gained considerable acceptance. It was known that bacteria and other micro-organisms were able to decompose proteins with the formation of numerous end-products. Among these was a group of compounds including cadaverine, putrescine, muscerine and neurine. Collectively they are called the ptomaines. It was shown that these disagreeable-smelling compounds were usually present in spoiled meats involved in outbreaks of botulism. From this arose the idea of "ptomaine poisoning", which still persists in the minds of many people.

However, in 1895, a Dutch scientist, investigating an outbreak of botulism caused by pickled ham, was able to isolate a specific type of bacteria which he described and named *Bacillus botulinum* (the bacillus related to sausage). At first those who had accepted the theory of ptomaine poisoning were hesitant to switch to some new idea. Slowly, however, the evidence and experimental proof began to accumulate, demonstrating beyond all doubt that "botulism" was caused by the poison produced by the bacteria that had been first isolated by the Dutch bacteriologist. Later the name *Bacterium botulinum* was changed to *Clostridium botulinum*, which is the name by which this organism is known today.

In Europe, where the earlier studies of botulism were carried out, most of the outbreaks were shown to be the result of eating smoked, salted, spiced or pickled meats and fish. Later, occasional instances of food poisoning, recognized as botulism, began to occur in America.

Instead of meats, the American outbreaks usually resulted from eating canned vegetables that had not been properly preserved. In Russia it was found that a great many cases followed the consumption of smoked or pickled fish products.

So far, these various outbreaks of botulism were confined to human beings. As our knowledge of the subject increased, it was found that many birds and animals developed diseases that had symptoms quite similar to human botulism; and furthermore that they were caused by toxins produced by bacteria that were almost identical to *C. botulinum*; and that the birds and animals acquired the disease by eating foods contaminated with these organisms.

In this way the picture gradually became more and more complicated. Instead of the simple "sausage poisoning", we have an increasingly wide range of foods becoming involved, and we know that similar diseases can develop in many different birds and animals. There was another series of observations that added to the complexity. Various outbreaks seemed in some way to be tied to specific geographic locations.

In order to clarify this increasingly complex picture of botulism, a tremendous amount of work was done in comparing the organisms isolated from outbreaks all over the world. First, the bacteriologist compared the characteristics of the bacterial cultures and came to the conclusion that they were all one species, *C. botulinum*. There were, however, some minor differences. Some strains would break down proteins and others would not; but these were not sufficient to divide the cultures into separate or different species.

Much more important were the studies that were made on the toxins produced by the different strains of *C. botulinum*. If a small amount of toxin from one culture is injected into a live animal, the body of the animal manufactures an antitoxin which will neutralize the toxin. The toxin and antitoxin fit together like two pieces of a jigsaw puzzle, and when they are combined the toxin is rendered harmless.

If the toxins from all the strains of *C. botulinum* were the same, the antitoxin produced by one strain should neutralize all the others. Experiments with animals proved this was not the case. At the present time, it is recognized that there are at least five types of botulinum toxin, each of which produces a specific and different antitoxin when injected into animals. These differences are so important that the organisms that produce them are also classified into five types: *C. botulinum A, B, C, D, and E.*

Only three of these Types, A, B and E, produce botulism in humans; Type C affects fowl, ducks, wild water birds and mink; Type D is confined to horses, sheep and cattle.

A tremendous amount of work has been done in trying to determine if there is any pattern of geographical distribution associated with these different types of *C. botulinum*. Because of the vast extent of the world's surface and the uneven distribution of the sampling, the picture is not complete. At the present time the results suggest something like this:

Type A. Apparently found in small numbers all over the world, wherever analyses have been made. In some areas it is more prevalent than in others. It is more abundant in the soils of the Rocky Mountains, the Pacific Coast and in Europe.

Type B. Also cosmopolitan, but apparently more abundant in central and eastern United States and in Europe.

Type C. Found in the United States, Australia and South Africa.

Type D. Found chiefly in South Africa.

Type E. Found mainly in the northern parts of our hemisphere, including the coastal regions of British Columbia, Alaska, Labrador, the Baltic area north of Europe, Russia and in northern Japan.

These are generalizations that may well be altered when more tests have been taken and more information is available. There is one fact, however, that is well established: *In one form or another, the organisms causing botulism are distributed in small numbers all over the face of the earth.*

Fishery products, in the rare cases where botulism is involved, may be the bearers of Types A, B, C, or E; but it is generally Type E that most concerns the fishing industry in Canada.

Some Important Characteristics of the Bacteria Causing Botulism

One aspect of the problem of botulism that has been under almost continuous study for 70 years deals with the characteristics, growth-requirements, and other activities of the bacteria themselves. It is not necessary to concern ourselves with most of the details of these studies. They are of interest chiefly to those who are directly involved in the diagnosis and control of botulism. There are, however, a few general observations that can add considerably to our understanding of the problems involved. These are as follows:

Resistant spores

Unlike most bacteria that infect animals or spoil food, *C. botulinum* belongs to a group of organisms that can change from their normal vegetable forms into smaller, compact, cyst-like cells that are often extremely resistant to heating, drying, irradiation and disinfectants. Once the cells have changed into this dormant, spore stage, it requires certain specific conditions to change them back again into active, vegetative cells that will grow and produce toxin.

These resistant spores greatly increase the difficulty of destroying *C. botulinum* in foods, or disinfecting a plant that has become comtaminated with them. They are not destroyed by pasteurization, and may even withstand the temperature of boiling water for several hours. The following figures are frequently quoted as the killing times for *C. botulinum* in dry and in moist heat:

TYPE OF HEAT	KILLING TIME IN MINUTES						
Moist Heat	At 212°F	221°F	230°F	239°F	248°F		
	300-530	40-120	32-90	10-40	4-20		
Dry Heat	At 248°F	266°F	284°F	302°F	320°F	338°F	356°F
	120	60	15-60	25	20-25	10-15	5-10

These figures are only approximations, because the spores of the different types of *C. botulinum* are not equally resistant to destruction. Type A and B, for example, are more difficult to destroy by heat than Type E. It is also a fact that the number of spores present and the material in which they are suspended, will influence the amount of heat necessary to destroy these spores.

It is because of the survival of heat resistant spores that improperly home-canned foods have been one of the most frequent causes of botulism in America. Before this was properly understood, even the commercial canners did not always heat their products sufficiently to kill the botulinum spores, and many deaths were brought about in this way. When the United States canning industry realized the dangers involved, they changed or modified their processing methods so as to entirely eliminate all chances for the survival of this particular organism.

Some foods can be sterilized by gamma radiation; but if meat or fish are subjected to enough radiation to destroy the spores of *C. botulinum*, the severe treatment would render them quite unpalatable.

It is believed that the natural habitat of all types of *C. botulinum* is in the soil, and that those found in the bottom muds of the ocean, and other large bodies of water, are probably washed down by the rivers and later distributed by the ocean currents. Most species of bacteria that have their origin in terrestrial environments usually do not survive very long in the salty water of the sea. Here again the spores of *C. botulinum* come into the picture. It is believed that their resistance permits them to survive for very long periods in the sea, and to finally settle out in the bottom muds.

In discussions dealing with botulinum spores, most of the emphasis is placed on their extreme resistance to changes in their environment. In addition to this, it might be well to point out that *spores form from normal vegetative cells only under certain conditions;* and later *these spores will change back to their more dangerous vegetative forms only under certain specific conditions.* The significance of this fact to the problem of botulism from fishery products will be discussed in a later portion of this paper.

Anaerobic growth

The next characteristic of *C. botulinum* is both important to understand and difficult to discuss in language that a layman can follow. A bacteriologist will tell you that it belongs to a group of bacteria that are "absolute anaerobes". A proper understanding of this term "anaerobe" is absolutely essential if we are to get anywhere in our attempt to estimate the potential danger of botulism poisoning to the fishing industry.

DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

Some people try to simplify the explanation by saying that "aerobes" are bacteria that will grow in the presence of air, and "anaerobes" are bacteria that will grow only in the absence of air. They illustrate this by saying that aerobic bacteria will grow well on the surface of fillets, and that anaerobic bacteria will grow in canned fish that have been vacum-packed to exclude air. Although this is essentially true, it is an incomplete explanation.

For example, if we were to examine a cupful of soil taken from the top four or five inches of our garden, we would find it teeming with actively growing anaerobes; and our garden is certainly not enclosed in a vacum-packed can! Or, we might have an inch or two of sterile broth in each of four uncorked test tubes, and then inoculate them with anaerobes. The result will be little or no growth of the bacteria in the broth. Now let us try a few simple experiments with these four tubes. The first we will leave untouched as a control; to the second we will add a drop of broth containing some aerobic bacteria; to the third we will add about 0.1% of a chemical called "sodium thioglycolate"; to the last tube we will add a few small pieces of sterile liver tissue. After a day or so, if we examine the four tubes, we will find no growth in the first, but the anaerobes will be growing merrily in the three other tubes, and they are all open test tubes, exposed to the atmosphere at the surface! It is obvious that it is not always essential to have anaerobes in a vacum-pack, sealed container before they will grow.

We can even reverse this experiment. Suppose our tubes containing the broth are evacuated and sealed so that no air can get in them. The anaerobes would flourish. If before sealing the tubes we added some sodium nitrite, or other so-called "oxidizing agents", the growth of the anaerobic bacteria would be very much retarded or might be stopped altogether.

In other words, although the removal of air is an important *contributing factor* for making conditions suitable for the growth of anaerobic bacteria, it is not absolutely essential. They can grow in open containers in which certain other types of bacteria are already growing; or to which certain reducing agents have been added; or to which certain types of plant or animal tissues have been added. If they are already in containers from which the air has been removed their growth can be stopped or retarded by the addition of certain oxidizing agents.

During the last 25 years we in the fishing industry have gradually become accustomed to measuring acidity and alkalinity in terms of the pH scale. We know that pH values above 7.0 are increasingly alkaline and below 7.0 increasingly acid. Chemists have also devised a somewhat similar scale for measuring oxidizing and reducing conditions in foods and other materials. These are called "Eh" values. We are getting a little nearer the truth if we say that aerobes are bacteria that can initiate growth in materials that have a relatively high Eh value, and anaerobes are bacteria that will only start growing when the Eh value has been reduced below a certain point. Removing the air reduces the Eh value; so does the addition of many kinds of reducing agents. Letting air back into an evacuated can raises the Eh value, so also does the addition of oxidizing agents.

In all foods, in the soil, and in almost all biological environments there are innumerable oxidizing and reducing compounds which counter-poise and react with each other. Under a given set of conditions, these opposing forces set up an equilibrium, giving us an Eh value. Change the conditions and the Eh value changes. Oxygen is one, but only one, of the stronger oxidizing agents which strives always to raise the Eh. What we must recognize is that in addition to oxygen there are many other factors that can raise or lower the Eh value.

Whether or not *C. botulinum* grows in a food and produces toxin, and whether or not dormant spores change back into the dangerous, toxin-producing vegetative cells, is dependent upon the Eh value of the material in which they are lodged. It must be a relatively low value to start them growing. From this it is obvious why canned goods and materials that are packed in a vacum, in plastic containers, pose particularly serious problems for those concerned with preventing botulism. It is not so generally realized that, in the absence of a vacum, certain other types of bacteria growing in a food may also produce conditions that will permit the growth of *C. botulinum* and the germination of its dormant spores. This is the reason why various types of pickled or fermented fish products, and particularly those to which vegetable products have been added, are occasionally the cause of outbreaks of botulism. You will remember that in the early history of "sausage poisoning" it was never the fresh meat, but always the processed or pickled products that caused the trouble.

Botulinum toxin

This is the most poisonous substance known to exist in nature. It has been calculated that 15 or 20 grams of pure toxin is sufficient to kill all the people in the world today. This rather gruesome thought is not a figment of the imagination of some writer of science fiction. It is a sobering fact that, "During the studies on bacterial warfare between 1942 and 1944, crystalline toxin was produced in quantities. It is somewhat disconcerting to contemplate the effects of introducing the toxin, by air, into the food and water supply of an enemy". (Quoted from page 502 of the 12th edition of Zinssers "Microbiology", published in New York in 1960).

It is understandable, therefore, why the biochemists have spent so much time in the study of this most extraordinary substance and why the physiologists have made a corresponding effort to understand its powerful action on the bodies of men and animals. It is now known that botulinum toxin is a protein, and that it acts in a manner similar to many of the enzymes that normally control the chemistry of our body. It apparently interferes with the release of acetylcholine, a compound found in the nerve cells which is required in the "sending of messages" through the nervous system. The result of its action is to cause paralysis of the muscles involved in respiration, which, if untreated, usually results in death.

It is now possible to produce antitoxins by injecting a "weakened" toxin into susceptible animals. If injected early enough, treatment by antitoxin will greatly reduce the seriousness of the poisoning. Unfortunately, it often happens that by the time the symptoms have been recognized it is too late for the antitoxin to be of much help.

As stated previously, the toxins from each of the different types (A, B, C, D, and E) of *C. botulinum* are not alike. They are neutralized by different antitoxins and they have certain other characteristics in which they differ from each other.

Unlike the spores of C. botulinum, the toxins are readily destroyed by heat. The exact amount of heat required varies among the different types. The toxin from Type A, for example, requires more heat for its destruction than the toxin from Type E. However, boiling for five minutes, or heating to 176°F (80°C) for 30 minutes, is sufficient to destroy the toxins from all types. It is important to realize that even though the toxins are destroyed by five minutes boiling, the spores are not. If such food is left standing, the spores may germinate and fresh amounts of toxin will be formed.

Prolonged exposure to direct sunlight and prolonged exposure to air will cause the toxins to deteriorate. The toxicity is also destroyed or reduced by alcohol, formaldehyde and free chlorine. It is interesting to note that in some outbreaks of botulism caused by food served at banquets, those who had partaken of considerable amounts of strong alcoholic beverages before consuming the contaminated food were unaffected, while the temperance advocates ended up in the grave.

In some cases, particularly with Type E, the toxin is sometimes formed in a relatively inactive state, but if this toxin with relatively low potency is acted upon by trypsin (a digestive enzyme that splits proteins) it may increase its toxicity many thousandfold.

Much more has been learned about these toxins than can be recorded in an article of this type and it is reassuring to know that this work continues. One point we must always remember: Botulinus toxin is something not to be taken lightly. It is the most potent poison known and generally results in an agonizing death for its victims.

Effect of other micro-organisms

In most experimental work, very special efforts are made to grow the cells of *C. botulinum* as pure cultures. This means that all other species of bacteria, as well as yeasts, moulds and other microscopic organisms, have been excluded. The toxins for experimental work are also produced under conditions where other micro-organisms have been excluded. Under ordinary conditions, where *C. botulinum* causes an outbreak of food poisoning in commercial or in home-produced foods, the growth of the bacteria and the accumulation of the toxin may be accompanied by the simultaneous growth and activity of many other species of bacteria. In the soil, in the sea bottom, and in other natural habitats of *C. botulinum*, the cells of these organisms will be even more widely interspersed with other types of microscopic life. It is of extreme importance, therefore, to know something of the effect of other bacteria on the growth and toxicity of these organisms.

This is a field in which relatively little work has been done, but the results that are available are extremely interesting.

Type C botulism affects birds, causing "limberneck" in chickens and similar diseases in ducks and other water fowl. It has been frequently isolated from the western marshes where wild ducks breed, and has been shown to be the cause of widespread mortalities among these birds. In

experiments carried out by workers in the U.S. Fish and Wildlife Service, it was found that *C. botulinum* Type C would not grow in open tubes of nutrient broth or in open pans containing common marsh vegetation. Where a culture of *Pseudomonas aeruginosa* was added, the organism grew and a virulent toxin was found. (*Ps. aeruginosa* is an organism commonly isolated from fresh water lakes and rivers and was shown to be abundant in the areas where the ducks were being poisoned). A similar experiment was tried by adding *Escherichia coli* with the *C. botulinum* in broth and marsh plants. Not only did the anaerobes fail to grow and produce toxin, but further experiments indicated that *E. coli* actually destroyed the toxin. In other experiments these same workers came across four other species of bacteria which destroyed the botulinum toxin in broth cultures at room temperature.

Algae and other green plants produce oxygen when growing in water. This helps prevent the production of the anaerobic conditions necessary for the growth of *C. botulinum*. In these same duck marshes, it was found that in areas where the green plants were growing vigorously, the oxygen content was high and *C. botulinum* failed to grow. In areas where the plants had died, the oxygen content was depleted and the toxin forming bacteria developed rapidly. It was possible to make a significant reduction in prevalence of "duck-sickness" merely by removing the rotting vegetation from the bottom of the marshes.

Although these observations were made on one of the types of botulism that is of more interest to those workers in wild life conservation than in fisheries, they do point out how complex the problem can become when one leaves the controlled experiments with pure cultures in the laboratory and comes in direct contact with conditions as they exist in nature.

Other experimenters have found that *E. coli*, *Aerobacter aerogenes* and *Proteus vulgaris* (organisms which are commonly found in the intestinal tract or associated with sewage pollution) were able to destroy botulinum toxin. *Streptococcus lactis* and *Lactobacillus casei*, bacteria that are commonly found in milk and cheese, were also shown to have a detoxifying action. *Bacillus subtilis*, one of the most widely dispersed aerobic spore-forming bacteria in nature, even more rapidly destroyed the toxin of *C. botulinum*.

It is not at all improbable that statements regarding the effect of other bacteria on the growth and toxin of *C. botulinum* will have to be changed or modified when different strains and types of this organism are involved; but we should not lose sight of the fact that in nature there are many other organisms that will help prevent the growth and toxicity of *C. botulinum*, as well as some that will encourage it. This should not be unexpected in light of the experience we have had with antibiotics in controlling the growth and activity of so many pathogenic bacteria.

Effect of salt, temperature and acidity on growth and toxin production

All general statements regarding the lowest temperatures, salt concentrations, or pH values permitting the growth of *C. botulinum* must be taken with considerable caution. First, because the different types of *C. botulinum* are not all equally affected by these factors. Second, because these factors are inter-related. For example, if the temperature at which a food is held is lowered, a smaller concentration of salt is required to suppress growth of *C. botulinum*. Other environmental conditions, the character of the food, and the type of the organism, must all be taken into consideration.

In spite of these statements there are some general observations that can be helpful.

C. botulinum Type E can grow and produce toxin at a considerably lower temperature than the other types which affect human beings. Where other conditions are favourable for growth, the temperature must be lowered below 39°F (4°C) to completely suppress Type E. Types A and B are checked at temperatures below 50°F (10°C). Rapid growth for all types occurs between 68°F (20°C) and 86°F (30°C). Increasing the temperature to 98°F (37°C) checks the growth of Type E, but not A and B. At 122°F (50°C) and above, growth and toxin production of all types are stopped. Repeated freezing has very little destructive action on the botulinum toxins.

In general, these organisms grow better in alkaline than in acid foods. Some workers have stated that the limiting values are pH 5 and 12, with optimum growth at pH 9. Others have shown that in certain foods, growth may occur at pH values as low as 4.5; and there is at least one record of *C. botulinum* growing at a pH value below 4.0 where it was accompanied by an actively growing yeast.

There are conflicting reports concerning the effects of sodium chloride on the growth of *C. botulinum*. Again, it is probable that these apparent contradictions result from experiments carried out with different types of *C. botulinum* growing in entirely different types of food. It would appear, however, that salt concentrations between 6 and

10% inhibit their growth under most conditions; occasionally they are not completely inhibited by 10%. The addition of sodium nitrite with sodium chloride greatly improves the growth-inhibiting action of salt.

Distribution of Clostridium Botulinum in Nature

Although we usually associate C. *botulinum* with various food products, these are not its normal habitat. Investigations carried out for more than half a century indicate that in small numbers these organisms are widely distributed all over the world, and their natural habitat is the soil. From the soil they are carried down by streams and rivers and may settle out in the muddy sediments at the bottoms of lakes and oceans.

Occasionally, in nature, conditions may arise which are particularly favourable for growth, and then, instead of being sparsely distributed, the cells and spores become very numerous. This is what sometimes occurs in the dead vegetable material in the bottom of certain western duck marshes. It may also occur when fish or animal flesh is left to decompose in the soil. Of course this is what occurs very occasionally when the spores of C. *botulinum* get into certain types of canned foods or fermented food products. In all these instances it is believed that the organisms come originally from the soil.

This raises some very interesting questions that so far have not been answered. Why, for instance, are the cells of C. *botulinum* so sparsely distributed in the soil? Why don't they multiply and become among the most numerous of the anaerobes normally found in enormous numbers in most soils? They are widespread over the face of the earth, and they produce the most potent poison known to man, yet they apparently never make the soil toxic. We never hesitate to drink water that continuously permeates through the soil; in fact, one of the most efficient methods of purifying water is to pass it through bacteria-laden soil.

Some people have tried to explain the relative sparsity of this organism in the soil on the basis of its strict anaerobic requirements. If this was the case, it should apply also to other soil anaerobes which are present in the soil in large numbers.

The numerous surveys that have been carried out indicate that the 5 or 6 recognized types of C. *botulinum* are not evenly distributed in soils all over the world. Some types are much more abundant in one geographic area than in another.

One of the most important recent discoveries in this field is that Type E is by far the most abundant in mud samples that have been examined from the bottoms of harbours, lakes and oceans. It is of special interest to our fishing industry to learn that the spores of Type E appear to be most abundant in the more northern waters of our hemisphere, and in the soil of adjacent land areas. Tests have been made on muds from the sea bottom off the coasts of British Columbia, Alaska, the Yukon, Labrador, the Scandinavian countries, Russia, and Japan have almost invariably shown Type E to be present. The following is a summary of some work that was carried out in the Baltic area: "Some of the more recent investigations in the Scandinavian countries have indicated a rather high incidence of C. *botulinum* Type E. About 84% of mud samples taken from the harbour of Copenhagen and 26% of soil samples taken from the adjacent city park contained the spores of Type E. This organism was also found in 50% or more of the marine muds taken close to the coast of southern Sweden. Soil samples from the adjacent land areas showed an equal or even greater incidence of C. *botulinum* Type E. It is suggested that the presence of this organism in the marine sediments is due to the fairly large quantities of soil which are washed down to the sea by rainfall and other precipitation". A very similar picture comes from Dr. C.E. Dolman, on our own West Coast, and from other workers in Russia and Japan.

The very real significance of these findings becomes evident when it is further learned that of the 48 recorded outbreaks of botulism in the whole world caused by Type E (up to 1962), 47 of them were shown to be caused by the consumption of fish or other sea food.

Other surveys have shown that C. *botulinum* Type E is found occasionally in the intestinal contents of both freshwater and marine fish.

It should be pointed out that the soil surfaces of the earth and the sediments at the bottom of our freshwater lakes and oceans cover an enormous area. The tests that have been carried out so far are the work of a mere handful of investigators. There are vast areas that remain to be explored. We know relatively nothing concerning the distribution of C. *botulinum* in many of the most important fishing areas of Canada.

DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

Outbreak of Botulism in Humans In the United States and Canada Between 1899 and 1941

Dr. K.F. Meyer, an outstanding authority on this disease, has collected information on all the reported outbreaks of botulism in humans in the United States and Canada during the 40 year period between 1899 and 1941. Of a total of 359 outbreaks there were only 2 in Canada.

It is interesting to see the proportion of the different types of food that are involved.

TYPE OF FOOD	NO. OF OUTBREAKS	PERCENTAGE
Fruit and Vegetables	268	74.6
Meats	27	7.5
Fish and Seafoods	24	6.6
Dairy Products	7	2.0
Unidentified Foods	33	9.3

We are interested chiefly in the 24 outbreaks caused by fishery products. What were the fish and how were they prepared? They were mostly home-canned salmon, tuna, clams and sardines. There were also a few from commercial packs: one each of salmon, tuna and crab, and four of clams and three of sardines. In addition, there were three from salted or pickled fish and two simply reported as "herring" and "sprats". During this 40 year period there was not a single report of botulism caused by eating fresh, frozen, or smoked fishery products.

When consideration is given to the many thousands of millions of pounds of fish that were consumed in the United States and Canada between 1899 and 1941, it becomes evident that the probability of any particular individual being affected by botulism from fishery products during this 40 year period was extremely small. If the improperly prepared home-canned fish were excluded, the chances would have been even less.

From the standpoint of those interested in the study of botulism, the really fascinating problem is not the two dozen outbreaks that did occur from fishery products during this 40 year period, but rather, why were there not a great many more? What good angel keeps the spores of *C. botulinum* from germinating and producing their deadly toxin in our endless tons of smoked, salted, marinated and otherwise processed fish, and why the entire absence of botulism from fresh fish during this same 40 year period?

Outbreaks of Botulism from Fishery Products In Canada Between 1899 and 1964

From the previous section it is seen that Dr. Meyer found records of only two outbreaks of botulism in Canada between 1899 and 1941. It is very probable that during the earlier periods the records were not complete and that there may have been a few more than the number reported. There are much better records for the two decades following 1940. These have been summarized by Dr. Dolman, of the University of British Columbia, who is the outstanding authority on botulism in Canada at the present time. During this period there were eight cases caused by fishery products and seven from people eating the flesh of sea mammals, mostly seal and whale meat.

Again it is interesting to see what kind of products were involved and how they were processed. These outbreaks were mostly from home-processed products: home-canned salmon, home-pickled herring and home-pickled trout. There was another outbreak from "salted Holland herring". All the remaining outbreaks were among Indians and Eskimos who had eaten salmon eggs, whale meat, seal flippers and other delicacies that were produced and stored under grossly unsanitary conditions. In other words, between 1940 and 1961 there were no outbreaks of botulism in Canada resulting from commercial fish caught in Canadian waters and processed in Canadian plants.

These records have been brought up to date by a recent statement by the Minister of Fisheries in the House of Commons. On October 30, 1963, he reported that during the past three years there had been no outbreaks of botulism in Canada resulting from the consumption of commercial fisheries products.

Botulism From Fisheries Products in Other Countries

To the consumers of commercially produced fishery products in Canada the problem of botulism is almost non-existent. What is the record for some of the other fish producing countries in the world?

In Great Britain there was only one case of botulism between 1935 and 1962 and this involved pickled fish. In the Scandinavian countries (Denmark, Norway and Sweden), there were 30 cases between 1901 and 1946 and these all involved various types of "processed" fishery products.

In Russia there have been many cases of botulism attributed to fishery products. In almost all instances where records were available, it has been "processed" fish that was involved, including smoked or salted herring, salmon, sturgeon, caviar, or marinated or fermented products — all eaten uncooked.

In Japan between 1951 and 1958 there were 22 outbreaks of botulism caused by fishery products. In every instance Type E was involved. Most of these were from one particular product, "izoshi", prepared from raw fish, cooked and malted rice, diced vegetables, vinegar, salt and spices, and allowed to ferment for 3 or 4 weeks before being eaten.

Wherever fish is eaten in our Northern Hemisphere, the picture is much the same. Fresh or frozen products are never involved. The E type of *C. botulinum* is almost invariably the responsible organism and the outbreaks are confined to 3 classes of products.

(a) Improperly canned products (home-canning).

(b) Grossly contaminated products that have undergone partial decomposition (eaten by Indians and Eskimos).

(c) Fermented or pickled products that are eaten uncooked.

Observations on Recent Outbreaks in the United States

In the past few years there have been several outbreaks of botulism from fishery products in the United States. Some of these involved canned fish, but the most publicity was given to outbreaks resulting from smoked fish. There were nine deaths and a number of non-fatal cases from the smoked fish.

As might be expected, these deaths alarmed the public health authorities in both the United States and Canada. Quite rightly, steps have been taken to try to prevent further outbreaks from these products. Everything possible should be done to stamp out the remotest chance of this very serious type of food poisoning. There is no question about that.

Unfortunately, however, the publicity surrounding these recent cases has tended to overemphasize some aspects of the problem and to almost ignore others that are equally important. Let us illustrate this by recounting something that happened at an international meeting of food bacteriologists a number of years ago. A very capable and well trained scientist read a paper dealing with *C. botulinum* that had been isolated from certain fishery products, including fish paste and canned pickled anchovies. The paper contained accounts of the type of toxin that was involved, the resistance of the spores to heat and the concentration of common salt required to suppress growth and toxin formation. There was little or nothing about the fish products themselves. After the paper had been read there was a question from someone in the audience: "Can the author tell us how the anchovies were prepared?" And the answer was: "They were not gutted and had clearly been badly prepared." He stated further, as a result of questioning, that these badly prepared canned anchovies had *not* been heated.

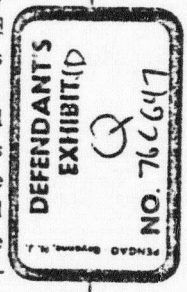
This scientist, speaking to other scientists, was principally interested in the characteristics of the bacteria and the toxin which he had isolated, incidentally, from some "canned anchovies preserved in curing brine". Until someone who was interested in other aspects of the problem started asking questions, he did not consider it worthwhile to say that the fish were infected, badly prepared, and that they were not heat processed. In fact, he finished his comments by saying: "The mere presence of the growth in the product proved that it was badly prepared."

Most scientists who investigate outbreaks of food poisoning are primarily interested in saving the lives of the poisoned persons who have eaten

the suspected food. It is essential that they identify the organisms and the type of toxin as rapidly as possible. Quite often they are not in a position to say very much about the food and how it had been prepared. This is unfortunate, because in the minds of most lay people all foods of the type involved are condemned or held suspect. They are not in a position to realize that it is not the food product that is to blame, but the gross carelessness of those who produced it, and that a hundred other foods treated in the same manner could have been equally dangerous.

To get back to the recent outbreaks in the United States, what are the facts?

In the case of the canned fish, it is known that after heat treatment the cans were cooled by immersing them in water that was contaminated by spores of C. *botulinum*. This, of course, is very poor practice. If there is any weakness in the seams, the vacum in the cans caused by rapid cooling will cause them to suck in small amounts of the cooling water. Modern canning procedure requires that the cooling water should be treated to render it sterile. Even better would be to use a super-pressure retort. This equalizes the pressure between the interior of the can and the interior of the retort, both during the sterilization and cooling of the cans and results in less strain on the seams during cooking and less chance of sucking in contaminated water during cooling.



In the case of the smoked fish, much has been made of the fact that this fish was in vacum packed plastic containers. It is quite probable that, if other conditions are favourable, this type of packaging would encourage the growth of C. *botulinum*. There is another aspect, however, that is known but has not been sufficiently emphasized. Smoking of meat or fish, as originally carried out, was a method of preservation. In most modern smokers the fish are first dyed to give them a "smoked-fish appearance" and are then lightly smoked to produce the smoked-fish flavour. This fish is perishable and requires temperatures close to freezing for its proper preservation. Some fish handlers fail to realize this and attempt to handle it as though it was the old-type, heavily-smoked product. The result is that smoked fish is usually among the most mishandled of our fishery products. Usually the strong odours and flavours that are characteristic of the smoked-fish products are enough to mask the early stages of deterioration that often takes place.

It has been reported that some of the smoked fish suspected of causing botulism was actually stored for several days at temperatures close to 100°F.

It was not the smoked fish that was at fault, nor can the method of packaging be held chiefly responsible; it was the careless way in which the fish was handled and stored.

CONCLUSIONS

The author of this review does not wish to underestimate the very real danger of *Clostridium botulinum* once it has got into a food, grown and produced its toxin. It does seem sensible, however, to point out that in spite of the widespread distribution of C. *botulinum* in nature, the occurrence of botulism from fishery products in Canada has been confined to a few dozen outbreaks in more than 60 years in which records have been kept. Furthermore, if we eliminate the improperly processed home-canned products, and the grossly contaminated and partially decomposed products consumed by our primitive peoples in the North, the few dozen instances shrink almost to nothing.

Surely there is something to be learned from this! The experience from the thousands of millions of pounds of commercial fish that have been produced in Canada since 1930 indicate that the chances of these organisms growing and producing their toxin in properly processed and properly stored fishery products is fantastically small. We need no new "breakthrough" in scientific investigation to eliminate botulism from fishery products in Canada. We need only to apply the knowledge that is already at hand.

Several decades ago the problem of botulism presented the canning industry with a far more serious problem than that faced by the fishing industry today. The canning industry rose to the occasion. They first learned the necessary facts and then they reorganized their methods of processing so as to entirely eliminate this danger.

The fishing industry can do the same. It is necessary to replace ignorance and fear with the facts that are already available. They will find out that the same precautions necessary to eliminate botulism will also eliminate other less serious types of food poisoning and at the same time bring to their customers fresher, better tasting products.

In Canada, every outbreak of botulism from fishery products has had a history of fish that had been poorly processed or grossly mishandled.

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References to Books and Articles With Special Reference to Marine and Fishery Products

1. Fatal outbreak of Botulism among Labrador Eskimos. J.C. Brocklehurst. British Medical Journal 2, 924, 1957.
2. Food Poisoning. G.M. Dack. University of Chicago Press, Chicago, Illinois. 1956.
3. Food Poisoning. E.B. Dewberry. Leonard Hill (Books) Ltd., London, 1959.
4. Botulism in Canada with a report of a Type E outbreak in Nanaimo, B.C. C.E. Dolman and D.E. Kerr. Canadian Journal of Public Health 38, 48, 1947.
5. Fish-borne and Type E botulism: two cases due to home pickled herring. C.E. Dolman, H. Chang, D.E. Kerr and A.R. Shearer. Canadian Journal of Public Health 38, 48-57, 1947.
6. The epidemiology and pathogenesis of Type E and fish-borne botulism. C.E. Dolman and H. Chang. Canadian Journal of Public Health 44, 231, 1953.
7. Type E botulism due to salmon eggs. C.E. Dolman, G.E. Darby and R.F. Lane. Canadian Journal of Public Health 46, 135, 1955.
8. Type E (fish-borne) botulism. A Review. C.E. Dolman. Japanese Journal of Medical Science and Biology 10, 383, 1957. (In English)
9. Recent observations on Type E botulism. C.E. Dolman. Canadian Journal of Public Health 48, 187, 1957.
10. Fish eggs as a cause of human botulism. C.E. Dolman, M. Tomsich, C.C.R. Campbell and W.B. Laing. Journal of Infectious Diseases 105 5. 1960.
11. Further outbreaks of botulism in Canada. C.E. Dolman. Canadian Medical Association Journal 84, 191, 1961.
12. Type E botulism: A hazard of the North. C.E. Dolman. "Arctic" – Journal of the Arctic Institute of North America, 13, 230, 1961.
13. *Clostridium botulinum* in Sweden and adjacent waters. A. Johannsen. Journal of Applied Bacteriology 26, 43, 1963.
14. Food poisoning in Japan. T. Kawakata. Chapter 11, Part 2, in Volume 2 of Fish as Food, edited by G. Borgstrom. Academic Press, New York, 1962.
15. Type E botulism poisoning. H. Meisel (Poland). Distributed by Office of Technical Services, U.S. Dept. of Commerce, Washington, D.C. 1961.
16. Type E botulism in Hokkaido, Japan. Y. Nakamura *et al.* Japanese Journal of Medical Science and Biology 9, 45, 1956.
17. Fifty years of botulism in the United States and Canada. K.F. Meyer and B. Eddie. Special Report, Hooper Foundation, San Francisco 1950.
18. On Type E botulism. O.H. Pedersen. Journal of Applied Bacteriology 18, 619, 1955.
19. Botulism in Arctic Alaska. Report of 13 cases with 5 fatalities. E.S. Rabeau. Alaska Medicine 1, 6, 1959.
20. Cultivation of anaerobes and oxidation-reduction potentials. G.B. Reed and J.H. Orr. Journal of Bacteriology 45, 309, 1943.
21. Botulism. H. Riemann. MSS No. 209 - Danish Meat Research Institute, Roskilde, Denmark, 1962.
22. Food poisoning caused by fish and fishery products. J.M. Shewan. Chapter 11 in Volume 2 of Fish as Food, edited by G. Borgstrom. Academic Press, New York, 1962.
23. Food-borne infections and intoxications. F.W. and L.P. Tanner. Garrard Press, Champaign, Illinois, 1953.

DEFENDANTS' EXHIBIT Q - BOOK ENTITLED: A REPORT TO THE FISHING INDUSTRY ON THE SIGNIFICANCE OF BOTULISM IN THE CANADIAN FISHERIES

Printed in Canada by the Queen's Printer
for exclusive distribution by the Fisheries
Research Board of Canada.

MEMORANDUM INCORPORATING FINDINGS OF FACT AND ORDER OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED AUGUST 17, 1976

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- - - - - - - - - - - - - - - - - - - -X

UNITED STATES OF AMERICA,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants

-and-

NATIONAL FISHERIES INSTITUTE,

Intervenor.

- - - - - - - - - - - - - - - - - - - -X

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MEMORANDUM INCORPORATING FINDINGS of FACT and ORDER

Appearances:

DAVID W. McMORROW, Esq. (DAVID G. TRAGER, Esq. United States Attorney, RICHARD A. MERRILL, Esq., Chief Counsel, FORREST T. PATERSON, Esq., Associate Chief Counsel, and ARNOLD I. FRIEDE, Esq. Assistant Chief Counsel, UNITED STATES FOOD and DRUG ADMINISTRATION, of Counsel) for the Government

JOSEPH H. EINSTEIN, Esq. and RICHARD S. MOREY, Esq. (Messrs. ARANOW, BRODSKY, BOHLINGER, BENETAR & EINHORN, and Messrs. KLEINFELD, KAPLAN & BECKER, of Counsel) attorneys for defendants and for intervenor

DOOLING, D.J.

The action was commenced on April 7, 1976, in substance to compel the defendants to comply with the Current Good Manufacturing Practice (Sanitation) regulations (21 C.F.R. §§ 128(a).1 to 128(a).7) by preliminarily and permanently enjoining defendants from processing hot smoked

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fish unless and until their manufacturing practices are brought into conformity with the Current Good Manufacturing Practice (Sanitation) regulations.

Defendants are engaged in Brooklyn in the business of receiving in interstate commerce frozen or iced white fish which are processed by defendants, that is, they are brined, smoked and cooked. The white fish are then held for distribution and distributed to stores as smoked white fish. The Food and Drug Administration inspectors made inspections of defendants' plant in July 1975 and again in February 1976, and on each occasion they found that defendants were not processing the smoked white fish in accordance with the regulations, primarily in that the process did not meet the heat and brining requirements of 21 C.F.R. § 128a.7(c)(4), (d)(2). Specifically the regulations required oven "cooking" the white fish at 180°F. for 30 minutes if the salinity of the fish was at 3.5% or at 150°F. for 30 minutes if the salinity was at 5%. There is no real dispute as to the facts of defendant's practice. The defendant did not heat the fish at 180°F. for a half hour nor did the salinity of the fish reach the 3.5% level.

The applicable portion of the regulation not

complied with reads as follows:

"(c) Presmoking Operation.

* * *

"(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

"(i) 3.5 percent if heat-processed as prescribed under paragraph (d)(2)(i) of this section; or

"(ii) 5.0 percent if heat-processed as prescribed under paragraph (d)(2)(ii) of this section.

* * *

"(d) Heating, cooking, smoking operation.

* * *

"(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

"(i) Not less than 180°F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c)(4)(i) of this section, ..., or

> "(ii) not less than 150°F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0% water phase salt in the finished product as prescribed in paragraph (c)(4)(ii) of this section."

The Current Good Manufacturing Practice (sanitation) regulations, dated November 2, 1970 and filed on November 12, 1970 for publication in the Federal Register of November 13, 1970 are not limited to salinity and temperature requirements. They include regulations with respect to unloading platform material and drainage; the provision of separate rooms for receiving and shipping, storing fish, pre-smoking operations including thawing, dressing and brining, and drying and smoking; the processes of packing and storage of the final product were to be carried out in separate rooms or facilities. There is a general requirement that the product be so processed as to prevent contamination by exposure to areas involved in earlier processing steps, to refuse, or to other objectionable areas. The regulations include equipment and utensil requirements with reference particularly to their being made of readily cleanable materials if they come into contact with the food products. The regulations require that adequate hand washing and sanitizing facilities be located in the processing

room or rooms or in an area easily accessible from them; signs are to be provided directing employees to wash and sanitize their hands after each absence from their duty posts. There is provision for periodical removal of offal, and requiring that offal, debris, or refuse must not be accumulated in or about the plant. Each day the utensils and product-contact surfaces of equipment must be rinsed and sanitized, and fish containers are not to be nested or handled during processing in a manner conducive to contamination. The cleaning and sanitizing of utensils and equipment are to be so carried out so as not to lead to contamination of the product. Fish are to be adequately inspected and only clean, wholesome fish are to be processed. Time and temperature controls are established with respect to refrigerating, thawing, spraying and washing fish. Fish are to be completely evicerated with the minimum disturbance of intestinal tract and thoroughly washed by a continuous spray system. The fish are to be brined in a solution that does not exceed 38°F. and the finished product is required to be cooled to 50°F. within 3 hours of cooking and to 38°F. or less within 12 hours after cooking. The finished product is to be handled only with clean, sanitized hands,

gloves or utensils. Shipping containers are to indicate the perishable nature of the product and to specify that the fish must be shipped, stored and held for sale at 38°F. or less until consumed. The product is required to be coded so that each lot's processing history can be traced. Other sections of the regulations require indicating thermometers on freezer and cold storage elements and require a point-sensitive, continuous temperature-recording device to monitor both the internal temperature of the fish and the ambient temperature inside the processing oven, each recording device record to be identified as to specific oven load and date processed.

The regulations thus closely supervise the handling of the fish not only by covering the processing procedures but also by setting requirements for equipment, general procedures and plant cleanliness.

The inspections of July 1975 and February 1976 not only demonstrated failure to comply with the time and temperature and brining exactions of the regulations, but also revealed a failure to maintain the pre-smoking brining stage at the requisite low temperature and failure to achieve the requisite post-smoking and cooking temperature levels.

The inspections at the defendant's plant disclosed further that it did not have all of the required indicating thermometers and temperature recording devices.

As already indicated, there is no claim of compliance with the regulations. The defendants have not in any substantial way contested the findings of the FDA inspectors and, indeed, have joined in a stipulation with respect to the findings on deviation from the salinity requirement of the regulations. On the contrary, defendants insist that the time-temperature-salinity standards of the regulations cannot be met without rendering the product unmarketable. The defense, then, has taken the form of an all-out attack on the validity of the regulations involved.

The attack centers on the unquestioned fact that only 21 U.S.C. § 342(a)(4) can be looked to as the source of the Food and Drug Commissioner's authority to adopt the regulations./ Defendants claim that it does not authorize any such regulation. It provides in seeming simplicity that

> "A food shall be deemed to be adulterated -
>
> "(a) ... (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

The contention takes a second form as an argument that in any event it would not suffice to show a violation of the regulation since the regulation is merely interpretive and not implementive of the law and, in consequence, the government must show that defendants violated the statute, reading the statute directly upon the facts; defendants say that no such showing of statutory violation has been made or attempted, for the Government has made no attempt to show any insanitary conditions at the plant if the word "insanitary" is read in its ordinary sense, the sense invited by its use in the same context with the words "contaminated" and "filth."

It is next argued that the nature and professed object of the regulations was to minimize the hazard to the public of Type E botulism and the risks of food borne infections in the consumption of smoked fish. It is argued that the regulations were put forward as the safest known processing parameters for preventing, through thermal destruction of spores of the bacteria, the outgrowth and toxin formation of Clostridium botulimum Type E. See Proposal of Part 128a for 21 C.F.R., 34 F.R. 17176 (October 16, 1969). It is argued that C. botulinum type Type E is

not a contaminant that reaches the fish during processing but is undeniably taken up by the fish from the lake waters which are their natural habitat, and that the known material has long since made it perfectly clear that the risk visualized is remote and unreal in the case of smoked white fish. Defendants argue that to the extent this problem has been associated with smoked white fish, it has been associated with vacuum packaged white fish. That is a mode of packing not followed by the defendants and which apparently is no longer employed in the industry at all.

The final phase of the attack rests on the argument that the regulation is unsupported by the record which it is entitled to call to its support. That record, it is argued, consists only of those materials submitted to the Commissioner by the industry and other interested parties in the course of the rule-making procedure and the materials brought forward and disclosed to the interested parties as being other materials consulted by the Commissioner in arriving at the regulations, to the extent that he did not rely solely on materials submitted in response to the notice of rule-making.

1. There is no doubt that the Current Good Manufacturing Practice (sanitation) regulations, as they are

frankly styled in 21 C.F.R. § 128(a).2, are adopted under 21 U.S.C. 342(a)(4), and that the Commissioner (as the delegate of the Secretary of Health, Education and Welfare, 21 C.F.R. § 2.120(a)(1), (15)) derived his rule-making authority in this relation solely from 21 U.S.C. § 371(a) which provides simply that

> "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."

Since the evidence is clear that the occurrence of C. botulinum Type E in white fish is not in fact or in the perspective of the statute a consequence of contaminations caused by unclean manufacturing practices or conditions, defendants' central argument is that the part of the Current Good Manufacturing Practice (sanitation) regulations here involved is, since oriented wholly to the sterilization of C. botulinum Type E occurring naturally in the fish and ingested in their native, water habitat, wholly unauthorized by the statute, and a nullity.

As defendants point out, Section 342(a)(4) has not the specificity found in Section 344(a) dealing with the issuance, in emergencies, of temporary permits. These permits impose conditions governing the manufacturing

process. They are issued when, in any locality, contamination with microorganisms is found to be occurring in the processing of any class of foods. And it could be said too that subdivision (4) does not use any of the general language used in other subdivisions of Section 342(a) which deal with substances in, the condition of, the source of, or the packaging of food: it does not use words like "poisonous," or "deleterious," or "putrid," or "decomposed," or "diseased," or "unfit for food." However it evinces a manifest and dominant purpose to deal with the cases in which the food has been prepared, packed or held under conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Describing the manufacturing condition as "insanitary" is secondary: the word is given operative content only by reference to the purpose of subsection (a)(4), that is, to provide against whatever condition of processing may render the product injurious to health or contaminate it with filth.

Only subdivision (4) of Section 342(a) treats a food as adulterated whether or not the food has in fact been contaminated or rendered injurious to health. Food

is considered adulterated if it has been prepared, packed or held under conditions that may have resulted in its contamination or in its becoming injurious to health. It is the only one of the subdivisions which directly deals with processing rather than with product in defining the circumstances in which the food product will be considered adulterated. For purposes of subdivision (4), it is irrelevant that, by any other tests, the food could not have been determined to have been adulterated and could not have been condemned. While Section 342(a)(4) may literally seem to deal only with conditions brought about by processing itself, the regulation under review, Part 128a, is specifically addressed to setting processing parameters to prevent the "outgrowth and toxin formation of C. botulinum Type E." Seen in the perspective of Part 128a's purpose and the purpose of subsection (a)(4), the use of the word "insanitary" in subdivision (4) of Section 342(a) is, at worst, inelegant, but it is not inadequate to include preparing, packing or holding conditions which permit a continuance of the outgrowth and toxin formation of the C.botulinum Type E in the product under process. Because such procedures may render the smoked fish injurious to health,

is considered adulterated if it has been prepared, packed or held under conditions that may have resulted in its contamination or in its becoming injurious to health. It is the only one of the subdivisions which directly deals with processing rather than with product in defining the circumstances in which the food product will be considered adulterated. For purposes of subdivision (4), it is irrelevant by any other tests, the food would have been determined to have been adulterated and therefore condemned. While Section 342(a)(4) may literally seem to deal only with conditions brought about by processing itself the regulation under review, Part 128a, is specifically addressed to setting processing parameters to prevent the "outgrowth and toxin formation of C. botulinum Type E." Seen in the perspective of Part 128a's purpose and the purpose of subsection (a)(4), the use of the word "insanitary" in subdivision (4) of Section 342(a) is, at worst, inelegant, but it is not inadequate to include preparing, packing or holding conditions which permit a continuance of the outgrowth and toxin formation of the C. botulinum Type E in the product under process. Because such procedures may render the smoked fish injurious to health,

the regulations proscribe cooking the fish at too low a temperature and/or for an insufficient length of time with inadequate salination. The approach of the regulations is that the temperature-time-salinity linkage is indispensable to preventing the outgrowth and toxin formation of the C botulinum Type E. It is beside the point that the bacterial infestation here is not one that invades the fish during the processing. A similar point under the earlier Act was met years ago in United States v. Forty Barrels, 1916, 241 U.S. 265, 279-281. It was suggested that if, as in the case of Coca Cola syrup, an offending substance was a formulary constituent, it could not be an adulterant because the term "adulterant" connoted additive intrusion. The Court gave that argument short shrift. And a generation or two ago in this Court, Judge Chatfield reached a very similar conclusion in United States v. Sprague, E.D.N.Y. 1913, 208 Fed. 419. Oysters packed and shipped in their natural unopened state which were found to harbor bacteria making them unfit for consumption were held to be "adulterated" within the meaning of the Act. The Court said (208 Fed. at 422)

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> "The ordinary use of 'adulteration' implies an actual addition to the original substance, through human agency. But the word as used in the section does not restrict this to addition by the hand of man, and if the adulteration of filthy, decomposed, or putrid substance has been added by nature, and is contained in the article to be shipped, it is adulterated in the eyes of the law."

Although the interpretation necessarily contended for by the Government puts a strain upon the language of the statute, it is a now familiar strain dictated by the manifest and dominant purpose of the statute - proscribing manufacturing processes that fail to deal effectively with a known risk of lethal infestation of food. The prescribed processing methods and controls are calculated to eliminate that risk.

2. Defendants argue that Part 128a of 21 C.F.R. is a merely interpretive regulation and is not coercive. The argument really is that Part 128a cannot be a substantive regulation having the effect of law. Defendants point out that the Act does not authorize any such substantive regulations under Section 342, although it does specifically authorize substantive regulations under those sections enumerated in 21 U.S.C. 371(e)(1). Those regulations are subjected, by Section 371(e) to strict promulgation requirements and broad opportunities for hearings. Section 371(e)

also requires that the determination be supported before the Secretary by detailed findings of fact based on substantial evidence of record, which are reviewable in the Court of Appeals rather than the District Court. The contention is that substantive effect may not, in this statutory setting, be ascribed to regulations adopted only under Section 371(a) and brought under judicial control only through 5 U.S.C. 501 et seq. and 701 et seq.

Whatever might have been the validity of the argument, it has been settled in this Circuit quite against defendants' contention by National Nutritional Foods Association v. Weinberger, 2d Cir. 1975, 512 F.2d 688, 694-698. Since the Food, Drug and Cosmetic Act does not require regulations not included under Section 371(e) to be made on the record after opportunity for an agency hearing, the rule making procedure invoked by the Commissioner in the present case is that of 5 U.S.C. 553 and the scope of review is correspondingly that of 5 U.S.C. 706(2), but without the requirement that the determination to adopt the regulation be supported by substantial evidence.

There might have been debate as to how far the implications of the Weinberger v. Hynson, Westcott and

Gunning, Inc., 1973, 412 U.S. 609, group of cases could be extrapolated. Those cases dealt with the new drugs application, approval and withdrawal-of-approval provisions of 21 U.S.C. 355; those provisions are precisely drawn and deal with an intrinsically factual-adjudicative context in specific applications to definite pharmaceutical substances, and the possibly "interpretive" regulations involved in the Hynson group of cases could be thought of as essentially procedural. But the resolution of the issue by Judge Mansfield in National Nutrional Foods is surely right, for the procedural regulations involved were what Mr. Justice Black once called "outcome determinative" and not merely procedural regulations.

So far as the form and language of Part 128a are concerned, they leave no room whatever for the argument that they were not intended to be "substantive"and coercive if it was lawful for them to have that effect.

3. Defendants argue that any possibility of injury to health from commercially prepared hot-smoked white fish was remote. Hence, defendants argue, there was no reasonable basis for concluding that the time-temperature-salinity prescriptions of Part 128a were necessary or appropriate to

prevent the processing methods currently in use from rendering the fish injurious to health.

It appears to be common knowledge in the industry that C. botulinum Type E is ubiquitous and that it occurs in the fresh water lakes from which white fish are drawn. Nearly all of the white fish of the industry in the greater metropolitan area come from Great Slave Lake and Winnipeg Lake; a small sample of white fish taken from Winnipeg Lake exhibited an 18 to 20% occurrence of C. botulinum Type E spores; a small sample from Great Slave Lake exhibited no spores. It appears also to be common knowledge in the industry that prior to 1963, cases of botulism that were traced to smoked white fish occurred but that there have been no occurrences since 1963. There appears also to be no controversy over the conclusion that vacuum packing of smoked fish, a practice no longer in use, was favorable to the spore development of toxin in smoked fish and was responsible for the 1960 and 1963 botulism outbreaks traced to white fish.

At the hearing in this Court evidence was presented to the effect that the bacteria do not normally occur in the flesh of the fish but rather invade the skin and intestinal

tract and migrate to the flesh, apparently in the course of eviceration and other preparation of the fish for brining, smoking and cooking. The same witness testified that since 1899 there had been ten outbreaks of botulism traced to C. botulinum Type E and that the toxin produced by the C. botulinum Type E spore development is a lethal toxin. It is common knowledge that botulism is an acute food poisoning marked by a high rate of mortality. (See, generally Exhibits P,P-1)

The Commissioner's proposal dated October 16, 1969, and published in the Federal Register on October 22, 1969, (34 F.R. 17,176) was prefaced by the statement that observations in smoked fish processing plants, made since 1963 by the FDA and other regulatory agencies, had shown that the industry had not consistently adhered to manufacturing processes that would minimize the hazard of Type E botulism and the risks of food borne infections in the consumption of smoked fish. It recited further that the Bureau of Commercial Fisheries of the Department of the Interior had suggested that adequate time-temperature-salinity parameters had not yet been established for each individual species smoked other than chub, and that the Bureau had recommended that

the proposed regulations be limited to plant sanitation and should exclude reference to processing techniques dealing with time-temperature relationships, or should describe good manufacturing techniques limited to smoked chub as processed in accordance with the food additive regulation governing the use of sodium nitrite (21 CFR § 121.1230). The prefatory statement continues

> "The Food and Drug Administration acknowledges that adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked. Much work has been done, however, on the thermal destruction of spores of Clostridium botulinum Type E, and to date the processing parameters presented in the proposal are the safest known from the standpoint of preventing outgrowth and toxin formation of C.botulinum Type E. It has been established that the public health hazard of C.botulinum Type E in smoked fish is not restricted to a single species. Examples of species found to contain spores of C. botulinum Type E are lake trout, salmon, black cod (sablefish), sole, sturgeon, and white fish.
>
> " The FDA has been, is, and will continue to be receptive to scientific data that documents adequate processing parameters or offers alternate processing parameters for any individual species of smoked fish. Data must be provided showing that the proposed processing parameters adequately minimuze risks of the public health hazard of poisoning by Type E botulism.

> "Currently, the situation exists whereby some processors base their manufacturing practices solely on the appearance and acceptability of the finished product quality to consumers rather than on any specific or controlled processing parameters that would minimize the health hazard of C.botulinum Type E or its toxins."

Then followed the text of the proposed part 128a.

It is not denied or deniable that the C.botulinum Type E hazard is present and persistent, that the development of toxin occurs, and that it is controllable within acceptable limits by thermal destruction of spores and by maintenance of the fish and the smoked fish product under refrigeration except during the smoking and cooking phase. Nor is it denied or deniable that the Type E toxin is lethal and that botulism poisoning has a high rate of mortality.

It may indeed be the fact that current product sampling of the cooked smoked white fish of defendants and of other producers in the greater metropolitan area did not disclose any evidence of botulinum spores, and that neither defendants nor others in the greater New York area have had any reported cases of botulism poisoning. That overlooks the fact that the regulations were imposedupon an industry already familiar with and using refrigeration and thermal

destruction of spores. The cooking and smoking process itself and the brining of the white fish inevitably worked in the direction of Part 128a and its no doubt sterner requirements. The controversy is solely about what time-temperature-salinity parameters are appropriate to give assurance of safety to the consuming public and the fish processors; it is not about the propriety of establishing such parameters.

It is not to be supposed that the 1960, 1963 occurrences of botulism in connection with hot-process smoked fish did not of itself cause changes in the industry. One of the communications to the Hearing Clerk in response to the notice of October 16, from the Association of Smoked Fish Processors, Inc., took exception to the FDA comment on industry practices saying

> " Since 1963, the processors of smoked fish have made significant changes in their facilities, equipment, utensils, processing practices and controls to improve the sanitation of their manufacturing operations in order to minimize the hazard of Type E botulism and the risks of food-borne infections due to the consumption of smoked fish. The effectiveness of this effort has been demonstrated by the absence of any botulism outbreaks since that time due to smoked fish, and to the minimum incidence of other food-borne infections rdated to this group of food products."

Defendants by letter to the Hearing Clerk concurred in the Association's general submission but in addition made the point that certain of the proposed requirements were impossible or impractical, specifying that the heating of certain fish types to high temperatures would destroy the product completely and that very cold brining temperatures would not permit the absorption of salt by the fish. As an alternative to the time-temperature procedures defendants suggested that specific processing procedures be established for each species after the completion of adequate work and experimentation.

The owner of a process for imparting smoky flavoring objected to the narrow definition of the term smoked fish and the process requirements but remarked,

> "Petitioner notes that the primary function of the new rule was to minimize the 'hazard of Type E botulism and the risks of food-borne infections ....' Thus the important limits of the Rule are the paragraphs relating to sanitation, the addition of salt to the product and the application of high temperature for a predetermined time to the fish product."

In its submission to FDA, the Bureau of Commercial Fisheries of the Department of the Interior Fish and Wild Life Service (BCF) favored deferring specific controls until

studies were completed with respect to the different species of smoked fish involved. The Bureau's Assistant Director stated

> "In our petition for nitrite, we showed that wholesomeness considerations could be more practically and adequately realized by reducing processing temperature and using suitable concentrations of nitrite and salt. Our work also suggests, for example, that if the minimum level of salt (sodium chloride) in the water phase of hot smoked fish is increased, this would allow for a significant reduction in the processing temperature required which in turn would maintain assurance of consumer safety without elimination of the marketability of most hot smoked fish products. In addition, the use of higher salt levels would lessen the dependency on temperature as a means to inhibit Clostridium botulinum Type E outgrowth, inasmuch as residual salt content can be readily monitored post processing.
>
> "As mentioned above, such an alternative of higher salt concentrations could be used as an interim measure until such time as on-going and future research to define processing parameters for other species are completed. We would be pleased to make specific suggestions to you that will provide on an interim basis a more practical alternative for the various species than the processing conditions specified in the good manufacturing practices."

A detailed suggestion made by BCF was that the 180° 30 minute 3 1/2% salt processing requirement be limited to smoked

chub and should present the alternative of processing the chub with salt and nitrite at lower temperature in accordance with 21 C.F.R.121.1230.

Similarly, neither the detailed response and commentary of the intervenor, National Fisheries Institute, Inc. nor its May 4, 1970 letter (Exhibit C), nor its letter of December 23, 1970 (Exhibit E) in any way suggested that the C. botulinum Type E risk was not real enough to justify adopting a Part 128a in some significant form.

4. The regulation as adopted is adequately supported by the record whether it is viewed as based on the Exhibit D tab A materials only or on all of Exhibit D. The regulation as modified from the original proposal is neither arbitrary nor capricious nor does it represent an abuse of discretion or any other deviation from law. The regulation was not adopted under a section enumerated under 21 U.S.C. 371(e) but rather under 21 U.S.C. 371(a). Therefore, it does not come within 5 U.S.C. 556 or 557 but rather within 5 U.S.C. 553(c), which simply requires that the agency, after considering the relevant matter presented, shall incorporate in the rules adopted a concise general statement of their basis and purpose.

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In adopting Part 128a under date of November 2, 1970 (published November 12, 1970, 35 F.R. 17,401) the Commissioner noted that the principal objection to the proposal had been that the process requirements in the proposed regulation could not be applied to all species of fish presently being smoked by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis. The Commissioner then continued

> "The Commissioner finds:
> (1) That although adequate times, temperatures and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of C. botulinum Type E; and (2) that since the public health hazard of C. botulinum Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay.
>
> " Therefore, having considered the comments received and other relevant material, the Commissioner concludes that the proposed regulations,with most of the suggested clarifying and technical changes incorporated, should be adopted as set forth below."

As noted above, Part 128a, as originally proposed,

would have provided in Section 128a.7(d)(2) that all hot-process smoked fish, after brining to 3.5% salinity, should be heated to 180°F. for a minimum of 30 minutes with the exception of smoked chub containing sodium nitrite as provided for in Section 121.1230 (which had a lower temperature parameter). As adopted, Section 128a.7(d)(2) provided an alternative of either cooking for not less than 30 minutes at 180°F. if the fish was brined to contain 3.5% water phase salt or for 30 minutes at not less than 150°F. if the fish had been brined to contain 5% water phase salt. The alternative for sodium nitrite treated smoked chub was retained.

The Association of Smoked Fish Processors, Inc., had argued that acceptable smoked chubs could not be prepared if the coldest portion of the slowest heating fish in the oven had to retain the temperature of 180° for 30 minutes and had argued that other varieties of fish were even more heat sensitive. The Association added

> "Work now underway by the Bureau of Commercial Fisheries on several varieties of fish have indicated very encouraging preliminary results with lower temperature processing in combination with specific salt and nitrite levels."

The Bureau of Commercial Fisheries, as seen in the quotation above, had suggested an alternative of higher salt concentrations as an interim measure until species parameters could be evolved.

The National Fisheries Institute, Inc., the intervenor, speaking for 26 firms actively smoking fish, had pointed out that smoked chub processed at 180° for 30 minutes had proved unacceptable to consumers, and that the matter had been resolved by permitting specified levels of sodium nitrite and chloride together with a lower operating temperature. It was said that if other fish were processed under similar high temperatures, the same marketing problems would arise. Speaking of work being done by the Bureau of Commercial Fisheries on white fish, sable and salmon, the Institute said

> "The experimental data indicates (sic) that considerably lower temperatures in combination with specific salt and nitrite levels will result in a smoked fish product that will be acceptable to the consumer, and also adequately minimize the risk of the public health hazard from Type E botulism."

Then the memorandum continued

> "In view of the unacceptable time temperature parameter of 180°F for 30 minutes, we request that the parameter of 150° F for 30 minutes and 5% salt in

> the water phase be established as an alternate procedure to that stated in the proposed regulation for an interim period until specific parameters can be established."

Specific language was suggested for Section 128a.7(d)(2) reading as follows

> "Hot processed smoked fish shall either contain not less than 3 1/2% salt (sodium chloride) in the water phase throughout the product and shall be heated by a process that will insure a continuous temperature throughout each piece of fish of at least 180°F. for at least 1/2 hour or shall contain not less than 5% salt in the water phase throughout the product and be heated by a process that will insure a continuous temperature throughout each piece of at least 150° F. for at least 1/2 hour, except that smoked chub containing sodium nitrite as provided for in 121.1230 of this chapter shall be processed in accordance with that section."

In its letter of May 4, 1970, the Institute did indeed refer to its proposal of the 150°F.-5% salt alternative and to the BCF's suggestion of that as an interim alternative and stated that, "Industry participants at the April 7, 1970 meeting ... pointed out that recent experimental work showed difficulties in meeting either of the sets of processing parameters." But in the Institute's December 23, 1970, letter (Exhibit E) written in seeking

modification of Part 128a, the Institute put it correctly when it said:

> "The industry recognizes that all processing requirements contained in FDA's good manufacturing practice regulations must be based on public health considerations. It is also recognized that these requirements cannot be reduced simply because the industry is unable to meet them. Such requirements should, however, be as flexible as possible to afford the industry as many alternative processing parameters as can be justified, based on public health considerations."

The Commissioner's modification of Section 128a(d)(2) to incorporate the 150°-5% alternative met the industry's most clearly expressed objection. The regulation is certainly not expressly interim in form, as BCF may be thought to have suggested, but regulations are not cut in stone. They are, inevitably, subject to continuous review. There is no indication that at any time before Part 128a was promulgated, specific parameters for different varieties of fish had in fact been developed and presented to the Commissioner as reliable substitutes for the generalized requirement which is complained of in the present case. BCF did not present a petition to amend the food additive (nitrite) regulation respecting smoked chub until March 22, 1971. They then proposed extending the regulation to white

fish and adjusting the processing parameters. The petition was incomplete since further studies were still in progress or in contemplation. The petition (FDA No.1A2671) was still under advisement at January 28, 1972. (Exhibit E)

Other modifications in the proposal were made in response to the industry's suggestions. The suggestion of the owner of the Zestismoke process (imparting smoky flavoring to fish) with respect to smoke flavored fish resulted in the inclusion in Part 128a of provisions embracing smoke-flavored fish, which are treated with salt and given smoke flavor by other than direct smoke action.

The proposed regulation required entirely separate, partitioned space for practically each distinct step in the processing of the smoked fish, and commentators objected that this was impractical and could not be accomplished in the industry's older plants. The objections were acceded to - to the extent of providing that four of the steps "should" be carried out in separate rooms or partitioned spaces and of making the separate room or partitioned space requirement mandatory only as to cooling and packing and storage of the final product. The provision governing inspection of raw fish was also somewhat relaxed. The

defrosting requirement was modified. The washing and spraying provisions were altered. The testing provision was relaxed. Finally the provision covering the cooling of the smoked fish after cooking was materially relaxed.

The Commissioner manifestly acted after considering the comments submitted to him, and before final adoption, he materially modified the proposal in accordance with the most important of the objections and suggestions submitted to him. No proceedings were ever instituted to review the regulations as adopted. Furthermore, no later proceeding has been initiated formally and pressed before the Commissioner directly to secure a modification of the regulation. The petition to the Commissioner (see Exhibit E) to extend the chub-nitrite regulation to white fish and, perhaps, other fish has evidently not yet been acted upon by the Commissioner. However, the industry has not elected, as it might have under 5 U.S.C. 704, 706(1), to treat non-action in the nitrite matter as an unlawful withholding or unreasonable delay of administrative action which should be corrected by a court. That does not mean that the FDA's failure to act on the later petition furnishes a ground for attacking its adoption of Part 128a; the two matters are

distinct in both time and substance. (There were, oddly, overtones throughout the court hearing that the present proceeding was an occasion to review the FDA's allegedly wrongful non-action on the nitrite petition, and that the non-action somehow backlighted the action the FDA had taken in adopting Part 128a.)

On the formal administrative record, therefore, the action of the Commissioner in adopting Part 128a was neither arbitrary nor capricious nor an abuse of discretion nor otherwise unauthorized.

The regulations were authorized by the statute and their enforcement denies no constitutional right to the parties defendant.

5. The defendants argue in substance that, to an indeterminate extent, those responsible for the determination to issue Part 128a in the form in which it was finally issued had resort to some or all of the material contained in defendant's exhibit D under tabs B through L. Apparently, it is not denied that the Commissioner had proper resort to the material under tab A, the more significant part of which had already been discussed, and which manifestly did effect modifications in the Commission-

er's original proposal. Defendants argue that the Commissioner has no right, either directly or through his subordinate personnel, to resort to anything that was not accessible to and notified to those in interest, so that they could meet any material contained in the undisclosed matter that might influence the Commissioner.

It should be said at once that the evidence indicates that the material under tabs B through L was retrospectively gathered from FDA files for any bearing which it could or might have had on the formation of Part 128a. It is not possible to say that the material specifically influenced any particular part of the regulation's language, but the very general and inclusive nature of the material collected indicates that it represents everything that could be located in FDA files germane to the subject matter of the regulation and dated before its issuance.

The basic difficulty with (a) the protestations of defendants and the intervenor that the material under tab A is not adequate to support the regulations and that the issues posed by the responses and comments of the industry were not resolved by determinations of fact and of scientific principle and (b) with the defendants' and

intervenor's protestations against the FDA's failure to disclose the materials at tabs B through L for discussion and refutation and (c) with the protestation that there could be no confidence as to which of the material the Commissioner may or may not have relied on - the basic difficulty is that they wholly mistake the occasion and the clear sense of the entire proceeding. The occasion was not one at which any one was disposed to or able to take the position that botulism was nothing to worry about, or that C. botulinum Type E was not ubiquitous in the fresh waters from which the fish were drawn, or that salination and thermal treatment were not basic in the hot-process smoked fish industry. It is not even deniable that to an indeterminate extent the industry was under loose self-regulation in the same respects covered by Part 128a - that is, in the use of salination and thermal controls. The industry had regulated itself not only to make an edible product but also in the interest of protecting the customers of the processors' customers from the risk of botulism. The post-1963 success of the industry was certainly a cause of self-congratulation. But the Commissioner could hardly be unaware that success begets a relaxation of vigilance, and that inspection reports could not demonstrate industry-wise

uniformity of procedures. Nor could the Commissioner guarantee the maintenance of self-imposed processing standards. And while much is said about the supposed want of procedural regularity in offering disclosure and an opportunity to challenge the tabs B through L materials, nothing has been brought forward either during the hearing in the present case nor, so far as counsel has surfaced it, in any other area, to indicate that a total reconsideration of the entire matter within FDA as of November 1970 could have resulted in any different regulation than the one then adopted. This case presents but one issue - in a case where precautionary regulations such as Part 128a (whether self-imposed or imposed by public authority) are admittedly imperative are those regulations shown to be either arbitrary or capricious or an abuse of discretion? The most that has been claimed is that further modifications in the regulations would be appropriate. And that claim has not been supported by bringing forward evidence to indicate that in November 1970 modifications existed that could have given the assurance of safety required in and assured by Part 128a. The nitrite alternative was not matured and supported; perhaps the chub regulation itself had not had time to settle in.

A survey of the material under tabs B through L discloses nothing which undermines the provisions of Part 128a and it is not material of a kind that could lend itself to contradiction. The material consists almost entirely of neutral investigative studies apparently conducted with considerable scientific and practical sophistication.

The first part of tab B is composed of four parts - three quarterly reports and a final report of work done in 1963-64 at the University of Wisconsin on C.botulinum Type E. The reports make particular reference to determining the source of the botulinum in smoked fish processed in the Great Lakes area and to the occurrence, persistence and disappearance of toxicity in detected botulinum. These reports were made to FDA under a contract, FDA-63-67. The remaining materials under tab B are quarterly reports and an annual report made to the FDA under contract EDA 64-44 by the University of Wisconsin, Department of Bacteriology. They concern the occurrence of C. botulinum Type E in the Great Lakes. The reports are again completely neutral scientific investigations, chary of conclusion, and they essentially confirm the idea

that C.botulinum Type E is more more common in some waters than in others. The reports, again, seek to measure the occurrence and persistence of toxicity and to differentiate between occurrences of the botulinum in water, fish and mud. The report also studies differences between botulinum occurrences in enclosed waters and in those waters linked to the Great Lakes themselves.

The papers collected under tab C concern the work of the Bureau of Commercial Fisheries at the Technological Laboratory at Ann Arbor, Michigan relating to smoked fish processing and handling. The 1964 paper is a draft of guidelines, most of which deal with sanitary precautions. The guidelines only concern handling of the fish from the fishing vessel through the plant, and attempt to insure the cleanliness of those procedures. The second paper is a 1967 draft of guidelines which dealt directly with processing of the fish including temperature and salinity requirements, and refrigeration standards. It contains nothing that would suggest modifications in Part 128a. Specifically it assumes the 180°-30 minute-5% parameters (although primarily as applied to chub processing).

Tab D covers a four phase study made in the New

York District FDA facility on the methods for hanging fish during the smoking process. The report was generally uncomplimentary to current smoked fish processing and it assumed the desirability of using the 180°-30 minute parameter. On the basis of experimental data derived from the FDA's own processing of several varieties of smoked fish, the report also concluded that a marketable product could be prepared within the 180°-30 minute parameter which would, in the judgment of many, equal the flavor of commercially produced fish but which - in general - would not have as good an appearance. The survey's general conclusion was that with its skills, the industry should be equal to producing marketable fish at the 180°-30 minute parameter. However, the principal emphasis of the study, if not its very purpose, was a solution to the problem of loss of fish from the hooks in the smoking and cooking steps. Some definite recommendations were evolved for reducing this loss.

Tab E covers the summary of a meeting held on July 11, 1968, at the University of Wisconsin. The meeting was intended to review the FDA smoked fish compliance program. It was in general conducted by FDA personnel and was

attended by Bureau of Commercial Fisheries representatives, representatives of the Food Research Institute, representatives of the University of Wisconsin, representatives of the National Center for Urban and Industrial Health, representatives of the City of Milwaukee Health Department (which was actually seeking to enforce a 180°-30 minute parameter), a representative of the Michigan Department of Agriculture, Food Inspection Division, the Chief of the Enteric Disease Unit of the National Communicable Disease Center, the Director of the Illinois Department of Health, Division of Food and Drugs, and food inspectors of the Wisconsin Department of Agriculture. The meeting reviewed numerous matters, including reports on the practical administration of various parameters under local laws. The meeting generally assumed as a base line the validity of the 180°-30 minute parameter in combination with a salinity in excess of 3% and refrigeration to 38° or less. However, the Bureau of Commercial Fisheries proposed the following processing parameters: (a) brining the fish so as to achieve a post-process product containing a water phase salt (sodium chloride)content equal to or in excess of 3 1/2% and a sodium nitrite concentration of 200 parts per

million, and (b) contolled heat processing so that internal product temperatures equalled or exceeded 160° F. for 30 minutes, and (c) temperature maintenance at or below 38°F during storage and distribution. The meeting discussed at length whether fish could and would be produced commercially at the 180°-30 minute-3 1/2 or 4% salinity parameters, and, if so, whether the fish would be saleable and whether the parameters could be attained in any large number of the existing processing establishments. There was no suggestion during the meeting that without a second salt such as sodium nitrite it would be safe to process the fish at temperatures lower than 180°. It was suggested that processing at 180° with only sodium chloride salinity might not be as effective as a combination of sodium chloride and nitrite at a lower temperature. The FDA point of view was presented at the meeting and it was noted that a year earlier, the Bureau of Commercial Fisheries had submitted to FDA a summary of research on botulism in smoked chubs which provided information on processing and handling procedures. The summary of meeting then continued -

> "The studies sponsored by BCF pointed up that heating fish at 180° for 30 minutes during processing, should bring about destruction of most type E spores, and if brining is accomplished in such a manner as to result in a salt content in excess of 3% in the aqueous phase of the loin muscle, and if the fish are held at 38° or less, the surviving spores will be prevented from growing out in the fish. These 'minimum requirements', along with storage temperatures, sanitation standards and labeling recommendations, were incorporated into 'Good Manufacturing Practice Guidelines', primarily for use by our [FDA] inspectors and Field Districts, but which were disseminated to industry. These Guidelines were reviewed and discussed with the National Fisheries Institute, who voiced intention to pass the recommendations on to their industry. The time-temperature-salt concentration and other recommended procedures have been made known to industry through workshops, seminars and, in many instances, in direct recommendations to plant management during course of inspections."

Tab F covers 72 articles, almost all of which are articles published in specialized periodicals concerning botulism, botulinum Type E and the spores and toxin of Type E. The articles are not only from United States publications but also from journals published in Canada, Japan, Russia, and the Scandinavian countries. The publications stretch back over the years to the 1940s. None of the papers, however, appears to deal with the temperature factor

except for one or two papers dealing with the effect of low temperatures (in the freezing range) on toxin development in vacuum packed fish.

Tab G is concerned with reports, for the most part printed and published, on the effect of temperature on C.botulinum Type E toxin formation and the survival and outgrowth of C.botulinum Type E in food products, including smoked fish. Particularly included is the published preliminary report of the Bureau of Commercial Fisheries on the experimental smoking of chub. At the time of that report, in November 1964, BCF was recommending processing at 180° for 30 minutes with 2 to 3% salt in the finished product as being practical in the case of chub. The published papers are for the most part research papers with varying results. However, the results do indicate that Type E botulinum spores, and, in consequence, toxin formation tendencies, did survive at high temperatures, and that temperatures in the order of 176-180° were always in active contemplation. Included at Tab G-5 is a May, 1967 Bureau of Commercial Fisheries paper by Graikoski adhering to the 180°-30 minute-3% salt combination and indicating that at 140°F a greater concentration of salt is necessary to

inhibit spore outgrowth. Graikoski stated that additional work was needed both to establish more firmly and to extend the general observations, especially in the temperature range from 140 to 180°F. The papers were inclusive in their consideration of the inhibitory effect of a combination of salt and nitrite, and of the effect of changes in the pH level of the brine and fish.

Tab H contains papers, for the most part printed and published, dealing, essentially from the chemical point of view, with regular salination and the effect of salt additives, including sodium nitrite. The papers also study the effect of changes in pH on spore production and the evolution of toxins. Tab I covers a published and printed 1961 article indicating that the outgrowth and toxin production of spores of C.botulinum Type E varies inversely with temperature in terms of days of incubation and that a critical refrigeration temperature exists in the range of 36 to 40°F.

Tab J embraces 23 papers, most of which were printed and published but some of which were apparently not widely published but, rather, were circulated in typed form. The papers cover a wide variety of botulinum studies. Included

were observations of human response to botulinum intrusions and to botulism itself and studies on the temperature sensitivity of the various types of C botulinum. Broadly, those studies indicated that Type E was more temperature sensitive than Types A and B, particularly in a range in the neighborhood of 176-180°F. The papers also included chemically oriented studies, indicating the significances of various types of salts, including sodium nitrite, and considering the effect of pH in botulinum solutions on outgrowth and toxin production. The papers are not limited to cooked and smoked fish but range more broadly, and include development of botulinum cultures generally. Certain of the papers are so poorly reproduced in the exhibit that, from the legible passages, it is not easy to be confident of the thrust of the papers, but the illegible ones appear to fall well within the boundaries of the foregoing description. The papers to some extent also consider anti-toxin materials.

The two items included under Tab K relate (a) to the incidence of C.botulinum Type E in smoked fish products (other than white fish) in the Pacific Northwest, and (b) to a means of detecting the presence of C.botulinum Type E.

The detection experiment used smoked white fish, chubs and other smoked fish as its base material. Tab L covers a 1970 Bureau of Commercial Fisheries circular entitled "Guidelines for the Processing of Hot-smoked Chub." The Guidelines, dated January 1970, are detailed but are written against the background of acceptance of certain processing parameters. The Guidelines assume the requirement of heating the chubs for 30 minutes at 160°F. with the loin muscle containing a concentration in the water phase of not less than 3.5% sodium chloride and a sodium nitrite concentration between 100 and 200 p.p.m., coupled with cooling of the chubs to 38°F. The parameters of the guidelines are of course those of 21 C.F.R. § 121.1230, first promulgated in August 1969 and amended in March 1970.

The material comprised under Tabs B through L was made available to defendants and presumably to the intervenor during the discovery stages of the case. The expert and the industry evidence introduced at the trial is not at war with anything contained in the Tab B brough Tab L material, and, in fact, added nothing of moment to what is in the formal record. Nothing in the B through L material has been or could well be pointed to as determining the

or 46.
Commissioner's conclusion,/as influencing it in such a way that, had it been known to be before him before the determination was made, it could have been met and refuted by other data. The problem did not and does not exist in that perspective or dimension. None of the B through L material suggests, nor do the defendants suggest, that precaution is unnecessary, that C.botulinum Type E is non-existent, that white fish come from untainted waters, or that there is any possibility that thermal treatment and salination and refrigeration can be dispensed with without danger to the industry or the public. If anything, the Commissioner's actions in modifying the original proposal demonstrate the openness of the proceeding. The very existence of the smoked-chub regulation (21 C.F.R. § 121.1230) authorizing the use of nitrite and a lower temperature demonstrates not only the industry's acquaintance with temperature-time-salinity parameters, but also shows the Commissioner's willingness to accede to scientific presentations.

However, there is no ground for considering the material under Tabs B through L as being in the nature of ex parte evidence secretly acted upon to the disadvantage of the class affected by the adoption of Part 128a. In

truth, the material contained under Tabs B through L comprises a reference library of the contemporary scientific work being done in the field, and to an extent, internal government views of the matter in the course of evolving a final administrative position. The internal evidence of the interdepartmental exchanges indicates that what the government was thinking about and doing was well known in the industry and to those who were actively interested in the inquiries being pursued as a result of the 1960 and 1963 poisonings, particularly the associations of interested persons. The rest of the material was published material which was either known to or readily accessible to any expert in the field to whom the members of the class to be affected by the regulation would naturally have turned for advice and assistance.

The difference in viewpoint between the Bureau of Commercial Fisheries and the FDA, made perfectly plain in the October 1969 notice, was hardly a secret and was forthrightly dealt with by the FDA. The difference in viewpoint reflects the difference in the roles of the two departments of government, for the FDA had to be concerned not with the hot-process smoked fish processors but with the public

safety and the sense of public security in the light of the 1960 and 1963 episodes.

5. Defendants and the intervenor argue that the parameters established by the regulation are impossible of attainment in commercial operations. The evidence introduced at the trial tended to that showing, but it failed to make the showing. It demonstrated only that the processors who testified were unable to meet the parameters without material change in their processing practices. The cross-examination brought out numerous techniques that the industry had not yet exploited, including forced draft heat circulation in the oven, the use of humidifiers, and fresh approaches to the problems of obtaining uniformity of temperature throughout the ovens. There were, further, indications that admittedly expensive modifications in processing procedures might well produce very different results from those obtained with the gas-fired gravity ovens. Such modifications include the use of electronic ovens, currently being introduced in the industry, and further work with control of oven humidity. There was certainly evidence that the electronic furnaces presently in use had not been so used as to meet the parameters and

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produce a satisfactory product. But the overall impression produced by the evidence was that the effort had not been complete, and that the processors had not attacked the problem with the resolution and industrial ingenuity that would have been summoned if they had acted in the recognition that they would simply have to comply with the parameters of Part 128a if they were to continue operation.

The evidence that a marketable product could not be prepared within the parameters suffers from essentially the same defect. The processors who testified were unable to produce marketable fish while staying within the regulation's parameters. But this was only shown to be true under their current processing practices. The taste test, although necessarily a narrow one, was carried out in as fair a manner as the trial situation permitted; if the results were accepted as a fair sampling of industry experience, they would lead to the conclusion that a product made under the parameters would not be marketable in the greater New York area nor probably in Florida. But that is hardly the issue. There are many other processors who may have mastered techniques that surmount the difficulties presented by the parameters. Moreover, the expectation cannot

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be that an identical product will be produced if the cooking temperature is materially increased and no compensating modifications, within the parameters, are introduced.

The industry itself had faced the risk that if C. botulinum Type E was not dealt with effectively, its business would be destroyed. If the material under Tabs B through L shows anything, it shows that when Part 128a was proposed in late 1969 it was high time that some such proposal was made, no less in the industry's interest than in the public's interest in personal safety. It was for the industry to devise methods of preserving marketability within the parameters, if, as was inevitable, it was unable to bring forward adequate evidence that some other approach would serve the public interest.

Finally, even if such a proposition could be demonstrated, it is not an answer to the regulation to say that marketable fish could not be processed under it. If that were the case it would simply mean that smoked white fish cannot be regarded as safe and that white fish can not be processed in their only marketable form without an unacceptable threat to public health. The ultimate fact appears to be that the industry has not been able to come

forward with alternative, safe processing means in which it has enough confidence to press them upon the Commissioner, and the industry has not exhausted the search for means of living within the parameters and still preparing marketable smoked white fish.

It follows that the United States is entitled to an injunction requiring compliance with the challenged parameters. However, there is much to be said for the defendants' contentions with respect to the other items of non-compliance with the regulation which were turned up in the course of the inspections. These appear to be rather ordinary deviations from compliance which are readily and once-and-for-all curable by positive action. The evidence indicates that the defendants have taken positive corrective action as to those deviations and, on the basis of the present showing, the final decree need not and should not contain mandatory provisions in those respects. These operational deviations from the regulation do not have the shape of the resolute non-compliance with the time-temperature-salinity parameters which characterizes defendants' conduct of its processing plant up to the time of the second inspection.

6. The defendants' trial evidence was taken over the Government's objection, reserving decision on the question of whether or not the Government was on firm ground in its argument that the regulation was not subject to collateral attack through a de novo hearing. Expansion of the scope of the hearing to include evidence addressed to the validity and soundness of Part 128a served the two-fold purpose of being a species of Overton type hearing and of throwing light on the question of whether there was any occasion for an Overton type hearing to determine whether or not the Commissioner had acted rationally. If the case is, as the Government contends, controlled by testing Part 128a against the formal record, whether limited to the tab A material or extended to the tabs B to L material, the conclusion must be that Part 128a is fully supported and adequately supported in the formal record. Viewing the whole record, including all the trial evidence, it is concluded (for all the evidence, on review, is seen to exclude the need for any further Overton type hearing), that there is no necessity for any further hearing in this Court or for a remand to the Commissioner for reconsideration in the light of matters not before him or not adequately considered

MEMORANDUM INCORPORATING FINDINGS OF FACT AND ORDER OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED AUGUST 17, 1976

by him at the time the regulation was adopted. Cf. National Nutritional Foods Ass'n v. Weinberger, supra, 512 F.2d at 703-704. Of course that is not to say that if the nitrite research has now significantly progressed, the time may not be ripe for a petition to the Commissioner for modification of Part 128a along the lines of the smoked-chub regulation. As noted earlier, such a regulation as Part 128a survives under ambulatory review as the literature in the field opens up new possibilities of analysis of the botulism risk or new means of coping with the spore formation and toxin production of C.botulinum Type E.

7. The Government will draft a decree in accordance with this opinion and either serve it on counsel for the defendants and for the intervenor with ten days notice of settlement, or, preferably, draft it in consultation with the defendants' and intervenor's counsel with a view to agreeing upon a form of decree - in the understanding that agreement on the form of the injunction does not to any extent imply acquiesence in its correctness as a disposition of the case.

It is so ORDERED.

Brooklyn, New York

August 17, 1976.

U. S. D. J.

NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR AN ORDER FOR A STAY PENDING APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUAL SKLAR,

Defendants,

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor.

X----------X

76 Civ. 647
(Judge Dooling)

NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR ORDER FOR STAY PENDING APPEAL

SIRS:

PLEASE TAKE NOTICE, that at 10:30 A.M. on October 6, 1976, at the United States Courthouse, 225 Cadman Plaza East, Brooklyn, New York, the undersigned will present the within Judgment to Honorable John F. Dooling, Jr., for signature and settlement and will simultaneously present to said Judge the within Order for a stay pending appeal.

Dated: New York, N.Y.
September 30, 1976

Yours, etc.

ARANOW, BRODSKY, BOHLINGER, BENETAR & EINHORN

By Joseph H. Einstein

Joseph H. Einstein
Attorneys for Defendants
Office & P.O. Address
469 Fifth Avenue
New York, N.Y. 10019
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NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR AN ORDER FOR A STAY PENDING APPEAL

TO:

DAVID TRAGER, ESQ.
United States Attorney
United States Courthouse
225 Cadman Plaza East
Brooklyn, New York 11201

KLEINFELD, KAPLAN & BECKER, ESQS.
1200 - 17th Street, N.W.
Washington, D. C. 20036

NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR AN ORDER FOR A STAY PENDING APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUAL SKLAR,

Defendants,

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor.

X----------X

76 Civ. 647
(Judge Dooling)

FINAL JUDGMENT

Plaintiff having commenced this action to enjoin defendants from violating certain provisions of 21 CFR 128a and the matter having come on for trial before this Court on May 17, 18 and 19, 1976, and this Court having rendered its Memorandum Opinion on August 17, 1976 incorporating therein Findings of Fact,

NOW, THEREFORE, IT IS ADJUDGED AND DECREED as follows:

1. That defendants Nova Scotia Food Products Corp., David Sklar and Emanuel Sklar and their officers, agents, servants and employees be and they hereby are restrained and enjoined from manufacturing and processing for distribution whitefish unless such whitefish are manufactured and processed by them in conformity with the regulations contained in 21 CFR 128a.7(c)(4)

(i) and (ii) and 21 CFR 128a.7(d)(2)(i) and (ii) as the same may from time to time be altered or amended.

2. That at least one (1) whitefish from each batch of hot-smoked whitefish manufactured or processed by defendants shall be tested by Herbert V. Shuster, Inc. (or such other laboratory as the parties may agree upon or the Court designate) to determine the sodium chloride content in the water phase of the loin muscle and reports thereof shall be furnished weekly to the New York District Office of the Food and Drug Administration, together with temperature records indicating the time and temperature at which such batches were cooked by defendants.

3. That said testing and report procedures shall continue in effect for the period of two (2) years from the effective date of this judgment.

4. That in accordance with the applicable provisions of law duly authorized Food and Drug Administration representatives shall be granted access to defendants' plant for the purpose of making such inspections at reasonable times and within reasonable limits and in a reasonable manner of the plant of defendants and for the purpose of obtaining samples of whitefish in order to determine whether defendants are complying with this Final Judgment.

5. That a copy of this Judgment shall be conspicuously posted at the processing plant of defendants

for a period of six (6) months.

6. That this Judgment shall take effect on October 30, 1978.

7. That jurisdiction of this Court is retained for the purpose of altering, amending, vacating, modifying or enforcing this decree as may hereafter be necessary and appropriate.

Dated: Brooklyn, New York
October , 1976

JOHN F. DOOLING, JR.
U.S.D.J.

NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR AN ORDER FOR A STAY PENDING APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

76 Civ. 647
(Judge Dooling

- against -

ORDER

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUAL SKLAR,

Defendants,

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor.

X----------X

Upon application of defendants, it is

ORDERED, that the Final Judgment herein dated shall not become effective prior to final determination of any appeal by defendants from said Final Judgment to the United States Court of Appeals for the Second Circuit and said Final Judgment is hereby stayed pending such appeal and final determination; and it is further

ORDERED, that this stay is conditioned upon defendants promptly filing an appropriate notice of appeal and taking all steps necessary to expeditiously prosecute said appeal, failing in which plaintiff may move for appropriate relief vacating or modifying this order.

Dated: Brooklyn, New York
October , 1976

JOHN F. DOOLING, JR.
U.S.D.J.

NOTICE OF SETTLEMENT OF DEFENDANTS' PROPOSED JUDGMENT AND APPLICATION FOR AN ORDER FOR A STAY PENDING APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

76 Civ. 647
(Judge Dooling)

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUAL SKLAR,

AFFIDAVIT

Defendants,

-and-

NATIONAL FISHERIES INSTITUTE,

Intervenor.

X----------X

STATE OF NEW YORK)
) ss.:
COUNTY OF NEW YORK)

DAVID SKLAR, being duly sworn, deposes and says:

1. I am the President of defendant Nova Scotia Foods Products Corp. and am also named as an individual defendant herein. I submit this affidavit in support and explanation of the the Judgment proposed by defendants herein and in support of defendants' request for a stay pending appeal. As will be shown, the decree proposed by defendants provides the government with all of the relief to which it is entitled and the government's proposed decree is overly broad and contains onerous provisions not called for in the circumstances. Additionally,

I respectfully submit that the defendants are entitled to a stay pending appeal.

2. The first major difference between the two proposed Judgments before the Court relates to their general coverage. In spite of the fact that whitefish was the only species of fish mentioned at trial or as to which the government adduced any evidence, plaintiffs would have the judgment cover all hot-smoked fish I respectfully submit that this is wholly inappropriate. This litigation involved only whitefish. There was not one scintilla of evidence at the trial as to any other type of fish. The government certainly offered no evidence that fish other than whitefish were not being prepared in accordance with the GMP. If the government desired relief as to fish other than whitefish, it should have offered evidence as to those other species at trial. There has been a total failure of proof as to fish other than whitefish and there is no rational basis for granting the relief which the government seeks as to all species of hot-smoked fish.

3. An injunction limited only to whitefish will have drastic adverse consequences on Nova Scotia. The broad relief which the government seeks by the sweeping injunction covering all forms of hot-smoked fish might well drive us out of business as it could affect forty (40%) percent of our sales. I respectfully submit that there is no reason to impose this drastic

penalty in view of the complete absence of any evidence in the government's case as to any kind of fish other than whitefish.

4. Perhaps the most significant feature of defendants' proposed decree is its provision for a two-year period before it becomes effective. I believe that this provision is necessary and appropriate if defendants are to be treated fairly in the circumstances at bar.

5. Before discussing the various reasons which support the requested delay, I should like to re-emphasize to the Court the fact that no person has ever been rendered ill by a piece of fish -- whitefish or other -- prepared by Nova Scotia in its many years in business. Since vacuum packaging was abandoned in 1963, there has not been a single case of botulism illness from whitefish -- or any other fish -- commercially smoked in the United States. Thus we are not dealing with a pressing or serious health hazard, but rather with a highly theoretical problem.

6. The last reported botulism problem from hot-smoked fish occurred in 1963 as a result of abusive handling of vacuum packed fish. The regulations at bar were not promulgated until seven years later, in 1970. Obviously, FDA felt no reason to rush. It was not until six years later, in 1976, that FDA first attempted to enforce the regulation. Again, obviously,

FDA felt no reason to rush. After thirteen years of footdragging by FDA, I submit most respectfully that an additional delay of two years can do no harm to plaintiff or to the public. The time requested, however, is critical to the protection and continued existence of defendants' business and the smoked fish industry.

7. Whitefish is an important and profitable part of our business and accounts for approximately ten (10%) percent of our sales. All hot-smoked fish makes up some forty (40%) percent of our sales. Our customers look to us to furnish all of their needs. The less we can do that the more we are handicapped in the market place and unable to compete and remain in business.

8. Nova Scotia employes some 35 persons -- mostly family men whose wives and children are dependent upon them for support. If we are forced to close, these people will be out of work with all of the attendant consequences. Our suppliers will lose customers, consumers will be denied our product and the economy will have suffered one more unnecessary blow inflicted upon it by the government. Given the lack of any injury to the public in the past thirteen years, FDA's sloth-like behavior and the economic and human impact of the relief sought, I respectfully submit that the two-year delay in enforcement is appropriate.

9. The period of two years has not been selected arbitrarily but rather is related to events, research and experimentation currently going forward.

A. At the present time, Dr. Eklund is completing additional research on the efficacy of nitrites as an inhibitor of botulism and the related problem of their safety for human consumption. This data should be available by the end of October 1976. I understand that based upon this information the smoked fish industry intends to re-petition the FDA for permission to use nitrites in all hot-smoked fish, including whitefish. FDA officials have estimated that it will take at least a full year for a decision to be rendered by FDA on this matter. Allowing some time for an overambitious estimate and time for a possible appeal to Court, two years is a conservative estimate of the length of time it will take for this application to be finally determined.

I am advised that the material which will be submitted to the FDA will demonstrate that the successful inhibition of the growth of clostridium botulinum can be achieved with the combined use of nitrites and salt and heat levels obtainable by industry while still producing a marketable product.

The apparent problem with respect to nitrites has not been its ability to inhibit the growth of botulinum but the possible problem of the presence of nitrosamines which are suspected carcenogenic agents. The research generated to date shows an excellent pattern of botulism inhibition without any nitrosamine problem. Thus, I

believe that the data which will be presented as to nitrites may provide a basis for a food additive regulation which will obviate the problem presented by the case at bar.

B. Additionally, there is research currently under way by Dr. Eklund which will demonstrate that inhibition of the outgrowth of botulinum spores may occur at salt-time-temperature parameters far lower than those set forth in the existing regulations. The smoked fish industry has provided additional funding for this research and it is being pressed as rapidly as possible. This research, which is admittedly in a very preliminary stage, indicates that inhibition can be achieved by cooking at 160°F for 60 minutes. This is a level which can be attained in the preparation of hot-smoked whitefish.

If on-going research proves this hypothesis to be correct -- and I believe it to be correct -- then in approximately one year we will be in a position to present a petition to the FDA for amendment of the existing GMP to these more realistic and attainable processing parameters. Given the time it takes FDA to act on these matters, I feel certain that it will be two years from now before we have any definitive action from FDA. Considering the complete absence of any demonstrated illness and the prior history of inaction by FDA, this is a most reasonable period of time to allow for appropriate action before the very drastic consequences

of the injunction the government seeks becomes effective.

C. Additionally, we are engaged in extensive research to determine whether it is possible for us to comply with the regulation as presently written and still produce a commercially marketable product. This work is progressing as rapidly as possible but we have not been successful. I am hopeful that future experimentation will point the way to a methodology of complying and producing a product which the consumer will accept.

We have repeatedly asked FDA to advise us as to methodology. They have refused. At trial, FDA created the misimpression that some form of technology -- known to FDA -- existed. The fact is that it does not. There is no magic formula and it will take a substantial amount of research and experimentation to find the methodology of compliance.

D. All of these efforts require large expenditures of time and expense. Very substantial sums have been expended in financing Dr. Eklund's research. Thousands of hours of time have been spent by processors in attempting to meet FDA's demands. This has meant that oven and employee time which could be used to produce marketable products has been deflected to these experiments. Further, thousands of pounds of fish have been burned up and discarded in the process. Defendants and industry as a whole are genuinely engaged in a massive

effort to find a solution. Time is the critical element.

10. All of these factors indicate why a delay for two years in the effective date of the injunction is necessary and appropriate.

11. Moreover, there are additional factors which must be considered.

A. Defendants are only one of several companies engaged in the processing of whitefish and other hot-smoked fish. If the restraints suggested by plaintiff are imposed upon it and no other industry member the result will be a highly unfair and inequitable burden imposed upon defendants.

B. Defendants have only an insignificant inventory of whitefish on hand. However, we were very much surprised by FDA's suggestion that this case embraced all types of hot-smoked fish. At the present time, we have some $75,000 worth of inventory on hand or ordered on firm commitments with respect to hot-smoked fish other than whitefish. This amounts to at least nine months of products. If an injunction were entered as to all forms of hot-smoked fish and if it were effective immediately, this $75,000 in inventory would be wasted and we would suffer a $75,000 loss.

12. The government's proposed decree sets forth a totally unreasonable, oppressive and unworkable method of procedure. I do not know where or how FDA derived

its form of decree but it is clearly more appropriate to non-perishable foods which can be tested at leisure than to highly perishable smoked fish which must be produced and marketed within a veryshort space of time.

13. The government's proposed decree would have us produce fish, submit it for testing and then wait until FDA decides to approve the fish before we could sell it. This procedure would destroy our ability to exist. Whitefish (and other hot-smoked fish) is a delicate product whose flavor and salability diminishes quickly after it is produced. If we must prepare our fish and then wait until FDA allows us to sell it, we will wind up with a totally unmarketable product fit only for the garbage can -- especially since our competitors will be free to sell a fresh, recently-made product without prior FDA approval.

14. The government's proposed decree would also impose a number of harsh and unwarranted economic and business sanctions upon defendants.

A. FDA's proposed Judgment requires that we submit a program to them describing how we intend to comply with the GMP and conditions our right to process hot-smoked fish upon FDA's approval of that program. The fact is, however, that FDA has not the vaguest idea of how to produce a marketable smoked whitefish in accordance with the GMP. For many years we have pleaded with FDA for advice as to how to produce a marketable product in conformity with the GMP. Each plea has been met with silence because FDA does not known how to comply.

To require pre-approval of our production techniques by an agency with no knowledge of these techniques is sheer folly. It would appear to be perfectly fair and reasonable to require FDA to make some showing that its regulation is possible of compliance.

B. FDA would also require the submission of hundreds of free samples for testing. The Court should realize that each whitefish we produce is sold by us for approximately $5.00. The government would have us submit vast quantities of whitefish for testing at great cost and expense without the least basis therefor in law or fact.

C. The government's proposed decree also fails to recognize the extensive steps which Nova Scotia has already taken to bring itself into compliance with what we regard as a totally unjust regulation. We have conducted extensive experiments to determine whether we could prepare whitefish at 180°F for 30 minutes and still have a marketable product. We have installed an in-plant salt testing facility so that we can check the salt content of each batch of fish before it is smoked. These steps are designed to insure that any future commercial production will be in compliance.

D. One of the most unfair of all of the government's provisions is that which would impose upon defendants the cost of FDA compliance checks. I know of no authority which justifies such a harsh penalty.

15. Nova Scotia has always acted openly and forth-

rightly. We have never attempted to conceal our conduct or deceive FDA. Yet FDA has proposed the kind of decree which would be appropriate only against the most repeated, conscious and deceitful violator of an injunction. There is no need for this drastic and vindictive sort of relief.

16. The decree proposed by defendants represents a fair and reasonable accommodation of the rights and interests of all concerned.

It contains an appropriate injunctive provision, reasonably limited to the violations shown in the courtroom;

It contains reporting provisions which will insure a constant flow of information to FDA;

It preserves the inspection and sampling rights granted to FDA by statute (21 U.S.C. §374);

It provides for a fair moritorium before the restraints involved are imposed.

17. In short, every legitimate governmental and public interest is protected while the rights of defendants and the smoked fish industry are also preserved. There is no reason for driving a viable economic entity out of business -- as the government would do -- where there are less drastic and more reasonable alternatives available.

18. Finally, defendants have submitted a request for a stay pending appeal. I respectfully submit that

given all of the circumstances involved in this litigation, including the lack of any illness, the thirteen-year long delay by FDA, the difficult questions of law and fact raised in this litigation and the economic reality of destroying a viable business entity and an entire industry, that the application for a stay pending appeal should be granted.

19. I respectfully request that defendants' proposed Judgment and stay pending appeal be entered and that the government's unduly harsh request for relief be rejected.

DAVID SKLAR

Sworn to before me this
30th day of September, 1976.

Joseph H. Einstein

JOSEPH H. EINSTEIN
Notary Public, State of New York
No. 60-1991825 Westchester County
Commission Expires March 30, 1977

PLAINTIFF'S PROPOSED DECREE OF PERMANENT INJUNCTION

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- X

UNITED STATES OF AMERICA,

- against -

Civil Action
No. 76-C-647

NOVA SCOTIA FOOD PRODUCTS CORP.,
DAVID SKLAR and EMANUEL SKLAR,

Defendants

DECREE OF
PERMANENT
INJUNCTION

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor,

- X

In accordance with the Court's Memorandum Incorporating Findings of Fact and Order, dated August 17, 1976, after trial, it is

ORDERED, ADJUDGED AND DECREED as follows:

1. That the Court has jurisdiction of the subject matter herein, and of all persons or parties hereto, and the complaint states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act;

2. That the defendants, Nova Scotia Food Products Corp., a corporation, and David Sklar and Emanuel Sklar, individuals, and each and all of their officers, agents, servants, employees, and representatives and any and all persons in active concert or participation with them or any of them, be perpetually restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts with respect to articles of food:

(A) Manufacturing and processing for distribution articles of food, namely, fish other than chubs, which fish are or are intended to be hot-process smoked fish, after shipment in interstate commerce, unless and until:

PLAINTIFF'S PROPOSED DECREE OF PERMANENT INJUNCTION

(1) Facilities, methods, practices, and controls used for the manufacture and processing of said foods by defendants are established and are capable of being operated and administered in conformity with current good manufacturing practice as set forth in regulations 21 CFR 128a.7(c)(4)(i) - (ii) and 128a.7(d)(2)(i) - (ii), specifically including the brining of fish in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished smoked fish, expressed as percent in the water phase of the loin muscle shall not be less than (a) 3.5 percent if heat-processed at not less than 180 degrees F. for a minimum of 30 minutes or (b) 5.0 percent if heat-processed at not less than 150 degrees F. for a minimum of 30 minutes.

(2)(a) Defendants report in writing to the New York District Office of the Food and Drug Administration what action they have taken to assure that the methods used in, and the facilities and controls used for, the manufacture and processing of food, namely fish other than chubs, are capable of being operated and administered in conformity with current good manufacturing practice regulations 21 CFR 128a.7(c)(4)(i) - (ii) and 128a.7(d)(2)(i) - (ii);

(b) Defendants select a testing laboratory which, by reason of equipment and trained and experienced personnel, is qualified to examine smoked fish for percent sodium chloride in the water phase of the loin muscle, and contract with said laboratory to perform such examinations on defendants' smoked fish;

(c) Defendants provide to the New York District Office of the Food and Drug Administration a written protocol for the selection of samples of smoked fish, other than chubs,

for sodium chloride analysis, which protocol shall describe procedures and designate responsible personnel and shall also include provision:

(i) for the selection of samples consisting of an adequate portion from each of 10 smoked fish for separate analysis for sodium chloride content, such samples to be selected from each of the first 10 consecutive batches of smoked fish processed for distribution by defendants subsequent to the entry of this decree and every tenth batch of smoked fish thereafter: Provided, that where any such analysis discloses that a fish contains less than the minimum percentage of sodium chloride required by regulation 21 CFR 128a.7(c)(4)(i) or (ii), such samples shall be selected for analysis from each subsequent batch until 10 consecutive batches have been found to contain not less than the percentage of sodium chloride specified by the regulation;

(ii) for the holding from distribution of each batch of smoked fish from which samples have been selected for analysis until defendants have received notification of the results of said analysis.

(3) The Food and Drug Administration notifies defendants in writing that defendants appear to have complied with the requirements set forth hereinbefore in paragraph 2(A)(1) and (2).

(B) Manufacturing or processing at defendants' plant, after compliance has been made with provisions of paragraph 2(A)(1) through (3) hereinbefore set forth, any article of food consisting of hot-process smoked fish, other than chubs, while held for sale after shipment in interstate commerce, which acts of manufacturing and processing result in said articles being adulterated within the meaning of 21 U.S.C.

342(a)(4) in that the facilities, methods, practices, and controls used for the manufacture and processing of said articles do not conform to and are not operated or administered in conformity with current good manufacturing practice in manufacturing and processing smoked fish, as prescribed by 21 CFR 128a.7(c)(4)(i) - (ii) and 128a.7(d)(2)(i) - (ii), to assure that said articles may not have been rendered injurious to health.

3. Defendants shall provide to the New York District Office of the Food and Drug Administration, not later than 5 days after the cooking of each batch of fish, other than chubs, smoked and distributed by defendants subsequent to the entry of this injunction, the results of analysis for sodium chloride content, if any, and copies of appropriate records showing the temperatures and the duration of such temperatures at which representative samples of each batch of such fish were cooked.

4. Duly authorized Food and Drug Administration representatives shall be granted free access to defendants' plant for the purpose of making such inspections of the plant, including all records and other things therein relating to the facilities, methods, practices, and controls used in the manufacture, processing, and distribution of raw, in-process, and smoked fish as the Food and Drug Administration deems necessary in order to determine that the requirements of this injunction have been or are being met, the costs of any such inspection to be borne by the defendants at the rate of $8.00 per hour and fraction thereof per representative for inspectional work, $10.00 per hour and fraction thereof per representative for laboratory and analytical work, $0.15 per mile

for travel expenses, and $39.00 per day for subsistence expenses where necessary.

5. That the defendants, Nova Scotia Food Products Corp., a corporation, and David Sklar and Emanuel Sklar, individuals, shall give written notice of the provisions of this decree to each and all of their officers, agents, servants, employees, and representatives, and any and all persons now or in the future in active concert or participation with them or any of them who assist or participate in the manufacture and distribution of the aforesaid articles of food.

6. That jurisdiction of this Court is retained for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate.

That the plaintiff, the United States of America, have and recover from the defendants the costs of this action, as taxed herein, to wit, the sum of $_____, and that the plaintiff have execution therefor.

Dated: Brooklyn, New York
, 1976

_____
U. S. D. J.

DEFENDANTS' SUPPLEMENTAL AFFIDAVIT OF JOSEPH H. EINSTEIN

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., et. al.,

Defendants.

X----------X

76 Civ. 647

(Judge Dooling)

DEFENDANTS' SUPPLEMENTAL AFFIDAVIT

STATE OF NEW YORK)
) ss.:
COUNTY OF NEW YORK)

JOSEPH H. EINSTEIN, being duly sworn, deposes and says:

1. I am a member of the firm of Aranow, Brodsky, Bohlinger, Benetar & Einhorn, attorneys for defendants herein. I submit this Supplemental Affidavit in connection with the proposed Judgments and Application For a Stay now before this Court.

2. As noted in the affidavit of David Sklar sworn to September 30, 1976, current research indicates that the problems presented to the defendants and the smoked-fish industry may be solved as a result of current industry financed research and the presentation of appropriate Petitions to FDA. I am annexing hereto as Exhibit "A" a copy of a letter received on October 12, 1976 from Dr. Eklund. The letter confirms

the various matters as to the state and timing of industry sponsored research as set forth by Mr. Sklar in his affidavit. Several salient elements should be noted:

A. The additional nitrite data will be presented to FDA this month. The overall picture is one of "excellent" inhibition with no related nitrosamine problem.

B. Research on alternative non-nitrite processing parameters is proceeding and the work done to date indicates that an alternative processing parameter of 160°F for 60 minutes is a real alternative to the current GMP. Such a processing parameter appears to be one which is achievable by industry. As Dr. Eklund's letter indicates, this research will require 6 to 9 months to complete.

3. The matters set forth by Dr. Eklund confirm the efforts of industry and the clear probability that those efforts will yield a result which will allow FDA to promulgate a far more reasonable GMP. If defendants and an entire industry are not to be destroyed, a reasonable delay is necessary. I, therefore, respectfully request that the Judgment herein contain a two-year effective date delay as requested by defendants.

JOSEPH H. EINSTEIN

Sworn to before me this
13th day of October, 1976.

KATHLEEN CULHANE
Notary Public, State of New York
No. 31-5872430
Qualified in New York County
Commission Expires March 30, 1978

EXHIBIT A TO EINSTEIN SUPPLEMENTAL AFFIDAVIT - LETTER FROM U.S. DEPARTMENT OF COMMERCE TO JOSEPH H. EINSTEIN, ESQ. DATED OCTOBER 7, 1976

U.S. DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
Utilization Research Division
2725 Montlake Blvd. E., Seattle, WA 98112

October 7, 1976

Mr. Joseph H. Einstein
Attorney-at-Law
Aranow, Brodsky, Bohlinger,
Benetar and Einhorn
469 Fifth Avenue
New York, N. Y. 10017

Dear Mr. Einstein:

Some time has passed since I last talked with you. I therefore thought that you would be interested in a brief progress report of our studies on the inhibition of Clostridium botulinum in smoked fishery products.

The nitrosamine studies of whitefish that were brined in different concentrations of sodium nitrite and sodium chloride have been completed. Nitrosamines were not detected in any of the samples at the 5 parts per billion level, which is the sensitivity level of the test. The data from this recent study is currently being incorporated into the whitefish petition and will be submitted in October 1976 to the Food and Drug Administration to request permission for the use of sodium nitrite in smoked whitefish. The use of nitrites (100-200 parts per million level) will permit the smoked fish processors to process whitefish to an internal temperature of 150-160°F for one-half hour with a final product concentration of 3.0 to 3.5% salt. When sodium nitrite is used in combination with sodium chloride, it becomes an excellent inhibitor of Clostridium botulinum.

We are also continuing our research to develop other alternatives to the current Good Manufacturing Practice Guidelines (GMP's). As you know, there is nothing magical about processing smoked fish to an internal temperature of 150° or 180°F for 30 minutes. The effectiveness of heating whitefish at 180°F for 30 minutes is based upon the heat destruction and injury of Clostridium botulinum type E spores. In experiments in which whitefish are inoculated with type E spores and processed at 180°F for 30 minutes, there are always spores that survive the process. These survivors are apparently heat injured and therefore are unable to grow and produce toxin in whitefish above 3.0% sodium chloride (water phase salt). We are therefore studying other time and temperature parameters between the existing GMP requirements of 150 to 180°F for 30 minutes in an effort to develop a process that will be as effective as the 180°F process in inhibiting C. botulinum. Results from our experiments with comminuted whitefish show that 3.5% water phase sodium chloride will inhibit type E spores at concentrations of

EXHIBIT A TO EINSTEIN SUPPLEMENTAL AFFIDAVIT - LETTER FROM U.S. DEPARTMENT OF COMMERCE TO JOSEPH H. EINSTEIN, ESQ. DATED OCTOBER 7, 1976

50,000 spores in 50 gram whitefish samples if the samples are processed to an internal temperature of 160°F for one hour. We are currently confirming these studies using steaks prepared from whitefish. These studies will soon be extended to other times and temperatures. You may be interested to learn that our studies of eviscerated frozen whitefish from Lake Winnipeg, Canada, show an average C. botulinum type E spore level of 0.4 per 100 grams of whitefish.

We have processed whole eviscerated whitefish to an internal temperature of 160°F for one hour and, in our judgment, a very satisfactory product can be produced. We will soon request members of the smoked fish industry to determine if this process will produce a satisfactory product in their processing plants.

We are currently studying procedures to improve the uniformity of salt distribution in smoked white fish. We believe that one of the critical points in consumer acceptability of smoked fish is the variation in the concentration of salt in the product itself. For example, the consumer will usually first eat the flesh closest to the surface of the fish. In this region the salt concentration is always the greatest. For example, in a sample that contains 3.5% salt in the loin muscle, the flesh near the surface may contain 5 to 7% salt. The consumer therefore object to the saltiness because of the 5 to 7% salt of the flesh near the surface and not because of the 3.5% salt in the interior of the fish. We have now developed a procedure with steaks and fillets that greatly improves the uniformity of the salt throughout the product. In one set of experiments the samples contained 3.7% salt in the outer layers of the flesh and 3.5% in the deepest part of the loin muscle. In approximately two weeks we will send all members of the smoked fish industry a copy of this procedure. This brining procedure will not only increase consumer acceptability but will also increase the safety from C. botulinum of the smoked product because it will eliminate areas of the fish flesh that may have low concentrations of salt.

We are encouraged by our results and hope that we may have comprehensive substantiation for alternatives to the GMP's within the next 6 to 9 months.

Sincerely yours,

Melvin W. Eklund

Melvin W. Eklund
Supervisory Microbiologist

FINAL JUDGMENT OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED OCTOBER 18. 1976

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- X

UNITED STATES OF AMERICA,

:

-against-

: 76 C 647

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR, : FINAL JUDGMENT

Defendants, :

-and- :

NATIONAL FISHERIES INSTITUTE, :

Intervenor. :

- X

This action came on for trial before the Court, The Honorable John F. Dooling, Jr., District Judge, presiding, and the issues having been duly tried and a decision having been duly rendered, it is

ORDERED and ADJUDGED

1. That the defendants, Nova Scotia Food Products Corp., a corporation, and David Sklar and Emanuel Sklar, individuals, their officers, agents, servants, employees, and attorneys and those persons in active concert or participation with them or any of them who receive actual notice of this judgment by personal service or otherwise are perpetually restrained and enjoined from manufacturing and processing for distribution whitefish unless such whitefish are manufactured and processed by them in conformity with the regulations contained in 21 CFR 128a.7(c)(4)(i) and (ii) and 21 CFR 128a.7 (d)(2)(i) and (ii) as the same may be from time to time in

force. A copy of the said regulations, as now in force, is attached to this judgment as Annex A.

2. That defendants report in writing to the New York District Office of the Food and Drug Administration within sixty days after the date hereof what action they have taken to assure that the methods used in, and the facilities and controls used for, the manufacture and processing of whitefish are capable of and are, if operated at all, being operated and administered in conformity with current good manufacturing practice regulations 21 CFR 128a.7(c)(4)(i)(ii) and 128a.7 (d)(2)(i) - (ii).

3. That defendants nominate a testing laboratory qualified to examine smoked whitefish for percent sodium chloride in the water phase of the loin muscle, to report the result of such examinations on defendants' smoked whitefish to the New York District Office of the Food and Drug Administration (NYDOFDA); and provide that Office with a written protocol for the random selection of samples of smoked whitefish for sodium chloride analysis, such protocol to establish procedures that will assure fair sampling that will present a fairly representative cross section of actual production; the nomination and protocol are to be furnished to NYDOFDA within ten days from the date hereof; if not objected to within ten days thereafter by NYDOFDA the protocol will be put into operation.

FINAL JUDGMENT OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED OCTOBER 18, 1976

4. That defendant shall select (in the manner provided in the protocol) at least one smoked whitefish from each of the first 10 consecutive batches of smoked whitefish processed for distribution by defendants subsequent to the effective date of this decree, and from every tenth batch of white-smoked/fish thereafter, for testing as provided in the protocol: Provided, that if any such analysis discloses that a whitefish contains less than the minimum percentage of sodium chloride required by regulation 21 CFR 128a.7(c)(4)(i) or (ii), then samples shall be selected for analysis from each subsequent batch until 10 consecutive batches have been found to contain not less than the percentage of sodium chloride specified by the regulation, at which time one in tem sampling will resume.

5. That defendants shall withhold from distribution each batch of white-smoked/fish from which a sample has been selected for analysis until defendants have received notification that analysis shows that the sample is in compliance with the salinity requirement of 21 CFR 128a.7(c)(4)(i) or (ii).

6. The effective date of this judgment as to paragraphs 1, 4 and 5 is that date, not later than 60 days from the date of this judgment, on which the nomination and protocol provided for in paragraph 3 have been agreed; paragraphs 2 and 3 are effective, subject to their internal time limits, on the entry of this judgment.

FINAL JUDGMENT OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED OCTOBER 18, 1976

7. That defendants shall provide to the New York District Office of the Food and Drug Administration, not later than 10 days after the cooking of each batch of smoked whitefish, processed and held for distribution by defendants subsequent to the effective date of paragraphs 1, 4 and 5 hereof, the results of the analyses made for sodium chloride content and copies of appropriate records showing the temperatures and the duration of such temperatures at which representative samples of each batch of such whitefish were cooked; such reports may be provided on a weekly basis to cover the previous week's processing provided no included datum relates to whitefish processed more than 10 days before the report date.

8. That, in order to secure specific compliance with this judgment, and wholly apart from and in addition to the FDA's statutory powers to gain access to, inspect, sample and otherwise proceed under the law and regulations in accordance with applicable regulatory procedures, defendants shall:

(a) Grant to employees of the FDA designated to conduct inspection for the purpose of determining whether or not defendants are in compliance with the terms of this judgment access to defendants' plant for the purpose of making such inspections of the plant, including all records and other

things therein relating to the manufacture, processing, and distribution of raw, in-process, and smoked whitefish as is necessary and appropriate to determine that the requirements of this injunction have been and are being met;

(b) Accept as evidence that the employees of FDA have been designated to conduct such inspection their production of (1) a letter from the United States Attorney for the Eastern District of New York directing and requesting that an inspection be made under this judgment; (2) the employees' FDA identification record cards FD Form 200a (21 CFR 2.121(p)(3)(1)); and (3) a copy of this judgment.

9. That the defendants, Nova Scotia Food Products Corp., a corporation, and David Sklar and Emanuel Sklar, individuals, shall give written notice of the provisions of this decree to each and all of their officers, agents, servants, employees, and attorneys, and those persons who are now or hereafter become participants with them in the manufacture and distribution of the aforesaid whitefish.

10. That jurisdiction of this Court is retained for the purpose of enforcing or modifying this decree and for the purpose of granting such other or additional relief as may hereafter become necessary or appropriate.

That the plaintiff, the United States of America,

FINAL JUDGMENT OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED OCTOBER 18, 1976

have and recover from the defendants the costs of this action, as taxed by the Clerk herein, to wit, the sum of $_____, and that the plaintiff have execution therefor.

Dated: Brooklyn, New York

October 15 1976.

Lewis Orgel
Clerk

by Thomas Blastelle
Ch. Deputy Clerk

Approved, October 15, 1976.

U. S. D. J.

FINAL JUDGMENT OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) FILED OCTOBER 18, 1976

ANNEX A

§ 128a.7

(c) Presmoking operation.

(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a maner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d) (2) (i) of this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d) (2) (ii) of this section.

(d) Heating, cooking, smoking operation.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

(i) Not less than 180° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (i) of this section, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (ii) of this section.

ORDER OF THE DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK (DOOLING, J.) DENYING DEFENDANTS' MOTION FOR A STAY PENDING APPEAL FILED OCTOBER 18, 1976

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- X

UNITED STATES OF AMERICA,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants,

-and-

NATIONAL FISHERIES INSTITUTE,

Intervenor.

- X

76 C 647

ORDER

For the reasons set forth in the decision both deferment of the effective date of the judgment and a stay pending appeal are inappropriate. The judgment as approved for entry has a somewhat deferred effective date in practical operation, and the interval before that date is ample to enable the defendants and intervenor to apply in the Court of Appeals for a stay. It is

ORDERED that defendants' motion for a stay pending appeal is denied.

Brooklyn, New York
October 15, 1976.

U. S. D. J.

NOTICE OF APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP.,
DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

X----------X

76 Civ. 647

NOTICE OF APPEAL

SIRS:

PLEASE TAKE NOTICE, that defendants Nova Scotia Food Products Corp., David Sklar and Emanuel Sklar and Intervenor, National Fisheries Institute, hereby appeal to the United States Court of Appeals for the Second Circuit from the Final Judgment herein dated and entered October 15, 1976.

Dated: New York, N.Y.
October 28, 1976

Yours, etc.

ARANOW, BRODSKY, BOHLINGER,
BENETAR & EINHORN

By _____
A Member of the Firm
Attorneys for Defendants-Appellants
Office & P.O. Address
469 Fifth Avenue
New York, N.Y. 10017
(212) 889-1470

NOTICE OF APPEAL

KLEINFELD, KAPLAN & BECKER

By Richard S. Mosey, Jr.
A Member of the Firm
Attorneys for Intervenor-Appellant
Office & P. O. Address
1200 Seventeenth Street, N.W.
Washington, D.C. 20036
(202) 659-2155

TO:

Clerk, United States District Court
Eastern District of New York
United States Courthouse
225 Cadman Plaza East
Brooklyn, New York 11201

STATE OF NEW YORK)
COUNTY OF NEW YORK) ss.:

ALLEN O HAYES, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age and resides at 162 Navy Walk Apt 6A Brooklyn N.Y. 11201.

That on the 20 day of Dec, 1976, deponent personally served the within JOINT APPENDIX VOLUME II OF II upon the attorneys designated below who represent the indicated parties in this action and at the addresses below stated which are those that have been designated by said attorneys for that purpose.

By leaving 2 true copies of same with a duly authorized person at their designated office.

~~By depositing true copies of same enclosed in a postpaid properly addressed wrapper, in the post office or official depository under the exclusive care and custody of the United Stated post office department within the State of New York.~~

Names of attorneys served, together with the names of the clients represented and the attorneys' designated addresses.

DAVID G. TRAGER
UNITED STATES ATTORNEY FOR THE
EASTERN DISTRICT OF NEW YORK
ATTORNEY FOR PLAINTIFF-APPELLEE
225 CADMAN PLAZA EAST
BROOKLYN. N.Y. 11201

Allen O. Hayes

Sworn to before me this
20 day of December, 1976

Michael DeSantis

MICHAEL DeSANTIS
Notary Public, State of New York
No. 03-0930908
Qualified in Bronx County
Commission Expires March 30, 1978